

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
<p>The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Service Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.</p> <p>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ORGANIZATION.</p>					
1. REPORT DATE (DD-MM-YYYY) 28-11-2008		2. REPORT TYPE Final		3. DATES COVERED (From - To) June 2006 to Nov 2008	
4. TITLE AND SUBTITLE A Comparison of National Policies on Research Involving Human Subjects to Facilitate Review and Approval of Collaborative Research				5a. CONTRACT NUMBER NA	
				5b. GRANT NUMBER NA	
				5c. PROGRAM ELEMENT NUMBER NA	
6. AUTHOR(S) Barrett, Geoff; Decot, Patty (ed.); Foster, Robert; Landolt, Jack; Landy, Rosemary; LaRose, René; McAnally, Ken; Pigeau, Ross; Poisson, Robert; Ratcliffe, Verity; Rennie, Scott; Rogers, Alison; Truscott, Susan; and Woodruff, Chris				5d. PROJECT NUMBER NA	
				5e. TASK NUMBER NA	
				5f. WORK UNIT NUMBER NA	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) USD(AT&L)/DDR&E/DUSD(S&T)/BioSystems; 3080 Defense Pentagon; Washington, DC 20301-3080, USA; Defence Science and Technology Organisations, Australia; Defence Research and Development, Canada; Head Quarters New Zealand Defence Force; Defence Science and Technology Laboratory, UK				8. PERFORMING ORGANIZATION REPORT NUMBER DOC-HUM-2-2008	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) The Technical Cooperation Program				10. SPONSOR/MONITOR'S ACRONYM(S) TTCP	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S) DOC-HUM-2-2008	
12. DISTRIBUTION/AVAILABILITY STATEMENT DISTRIBUTION STATEMENT A. Approved for public release; distribution is unlimited.					
13. SUPPLEMENTARY NOTES This document contains information authorized under the auspices of The Technical Cooperation Program (TTCP) for unlimited release and distribution.					
14. ABSTRACT The purpose of The Technical Cooperation Program (TTCP) is to facilitate the collaboration between member nations regarding defence science and technology. This program allows its five member nations to share information and undertake joint research. Differing national policies on human research complicates collaboration. TTCP Human Resources and Performance (HUM) Group established Action Group (AG) 25 to review each nation's policies and procedures for approving human subject research and to provide a document to support TTCP members in obtaining their nation's approval for collaborative projects. The document identifies and compares the major national and defence policies. It also includes frequently asked questions and answers. The report also contains a list of national references and website links useful to TTCP researchers.					
15. SUBJECT TERMS The Technical Cooperation Program, TTCP, research, human subject, ethics, research policy					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 83	19a. NAME OF RESPONSIBLE PERSON Patty Decot
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (Include area code) 703-588-7402



The Technical Cooperation Program

Australia - Canada - New Zealand - United Kingdom - United States of America

TTCP DOCUMENT

A Comparison of National Policies on Research Involving Human Subjects to Facilitate Review and Approval of Collaborative Research

November 26, 2008

DOC - HUM - 2 - 2008

“This document contains information authorized under the auspices of The Technical Cooperation Program (TTCP) for unlimited release and distribution.”



TABLE OF CONTENTS

TABLE OF TABLES	iii
DOCUMENT CONTRIBUTORS	iv
EXECUTIVE SUMMARY	v
1. INTRODUCTION	1
2. NATIONAL POLICY FRAMEWORK FOR RESEARCH INVOLVING HUMAN SUBJECTS	2
2.1. National Policy Framework for Australia.....	3
2.2. National Policy Framework for Canada	6
2.3. National Policy Framework for New Zealand.....	7
2.4. National Policy Framework for the United Kingdom.....	9
2.5. National Policy Framework for the United States	10
3. NATIONAL POLICY FRAMEWORK REGARDING THE DEFINITION OF HUMAN RESEARCH.....	12
3.1. National Policy Framework Regarding the Definition of Research for Australia.....	13
3.2. National Policy Framework Regarding the Definition of Research for Canada	15
3.3. National Policy Framework Regarding the Definition of Research for New Zealand...	17
3.4. National Policy Framework Regarding the Definition of Research for the United Kingdom	18
3.5. National Policy Framework Regarding the Definition of Research for the United States.....	20
3.6. Comparison of the Scope of the Definition of Research	23
4. NATIONAL POLICY FRAMEWORK REGARDING RESEARCH LIABILITY	25
4.1. National Policy Framework Regarding Research Liability for Australia.....	26
4.2. National Policy Framework Regarding Research Liability for Canada	27
4.3. National Policy Framework Regarding Research Liability for New Zealand.....	28
4.4. National Policy Framework Regarding Research Liability for the United Kingdom	29
4.5. National Policy Framework Regarding Research Liability for the United States	31
5. NATIONAL POLICY FRAMEWORK REGARDING DATA COLLECTION, USE AND SHARING	32
5.1. National Policy Framework Regarding Data Collection, Use and Sharing for Australia.....	33
5.2. National Policy Framework Regarding Data Collection, Use and Sharing for Canada.....	35
5.3. National Policy Framework Regarding Data Collection, Use and Sharing for New Zealand.....	37
5.4. National Policy Framework Regarding Data Collection, Use and Sharing for the United Kingdom.....	39



5.5. National Policy Framework Regarding Data Collection, Use and Sharing for the United States	41
6. CONSIDERATIONS FOR INFORMED CONSENT WHEN COLLABORATING WITH OTHER TTCP NATIONS	44
6.1. National Policy Framework Regarding Informed Consent for Australia	45
6.2. National Policy Framework Regarding Informed Consent for Canada.....	46
6.3. National Policy Framework Regarding Informed Consent for New Zealand	47
6.4. National Policy Framework Regarding Informed Consent for the United Kingdom.....	47
6.5. National Policy Framework Regarding Informed Consent for the United States	48
6.6. Common Key Elements Regarding Informed Consent	49
7. FREQUENTLY ASKED QUESTIONS (FAQ) IN HUMAN RESEARCH ETHICS	53
8. CONCLUSION.....	59
9. REFERENCES	61
10. GLOSSARY	68
APPENDIX 1. Additional UK National Policies	71
APPENDIX 2. Canadian Forces General Order 198/08.....	75



TABLE OF TABLES

Table 2-1. National Policy Framework for Australia	5
Table 2-2. National Policy Framework for Canada	7
Table 2-3. National Policy Framework for New Zealand.....	8
Table 2-4. National Policy Framework for the United Kingdom	10
Table 2-5. National Policy Framework for the United States.....	12
Table 3-1. National Policy Framework Regarding the Definition of Research for Australia	14
Table 3-2. National Policy Framework Regarding the Definition of Research for Canada	16
Table 3-3. National Policy Framework Regarding the Definition of Research for New Zealand.....	18
Table 3-4. National Policy Framework Regarding the Definition of Research for the United Kingdom	19
Table 3-5. National Policy Framework Regarding the Definition of Research for the United States	22
Table 3-6. Some Common Activities That May or May Not Be Considered Human Subject Research.....	23
Table 4-1. National Policy Framework Regarding Research Liability for Australia	27
Table 4-2. National Policy Framework Regarding Research Liability for Canada	28
Table 4-3. National Policy Framework Regarding Research Liability for New Zealand	29
Table 4-4. National Policy Framework Regarding Research Liability for the United Kingdom	30
Table 4-5. National Policy Framework Regarding Research Liability for the United States.....	31
Table 5-1. National Policy Framework Regarding Data Collection, Use and Sharing for Australia.....	34
Table 5-2. National Policy Framework Regarding Data Collection, Use and Sharing for Canada.....	35
Table 5-3. National Policy Framework Regarding Data Collection, Use and Sharing for New Zealand	37
Table 5-4. National Policy Framework Regarding Data Collection, Use and Sharing for the United Kingdom.....	40
Table 5-5. National Policy Framework Regarding Data Collection, Use and Sharing for the United States	43
Table 6-1. Elements to Include in a Common Informed Consent Form when Collaborating with Other TTCP Nations	49



DOCUMENT CONTRIBUTORS

*Dr. Geoff Barrett	Dstl, United Kingdom
*Ms. Patty Decot	DoD, United States (Lead Author and Editor)
*Dr. Robert Foster	DoD, United States
*Dr. Jack Landolt	DRDC Toronto, Canada
LtCol Rosemary Landy	DSTO, Australia
*Mr. René LaRose	DRDC, Canada
Dr. Ken McAnally	DSTO, Australia
*Dr. Ross Pigeau	DRDC Toronto, Canada
LtCol Robert Poisson	DGHS, Canada
Lt Verity Ratcliffe	HQNZDF, New Zealand
*Cdr Scott Rennie	HQNZDF, New Zealand
*Ms. Alison Rogers	Dstl, United Kingdom
Ms. Susan Truscott	DRDC, Canada
*Dr. Chris Woodruff	DSTO, Australia

* ACTION GROUP 25 MEMBERS

Australia	Dr. Chris Woodruff
Canada	Dr. Ross Pigeau
	Mr. René LaRose
	Dr. Jack Landolt
New Zealand	Cdr Scott Rennie
United Kingdom	Dr. Geoff Barrett
	Ms. Alison Rogers
United States	Dr. Robert Foster
	Ms. Patty Decot



EXECUTIVE SUMMARY

The purpose of The Technical Cooperation Program (TTCP) is to facilitate the collaboration between member nations regarding defence science and technology under a Memorandum of Understanding (MOU). TTCP has been very successful in providing a framework to achieve this collaboration by allowing researchers from its five member nations to share information and undertake joint research under various project arrangements and data exchange agreements. However, the differing national policies on conformance to ethical requirements in human research complicates collaboration as regards the establishment of appropriate procedures for the ethical protection of human subjects in the research. TTCP does not have templates for a universally acceptable research protocol or consent document pertaining to human research, nor is there a comparison of national policies that address the unique national requirements covering research involving human subjects.

TTCP Human Resources and Performance (HUM) Group established Action Group (AG) 25 to review each nation's policies and procedures for approving research involving human subjects and to provide a document to support TTCP members in obtaining their nation's approval for collaborative projects. AG25 identified four key topics where national policies differed: providing for liability consideration, applicability to various kinds of research activities, sharing data, and having a common informed consent document.

The document identifies and compares the major national and defence policies that researchers must follow to have a compliant protocol for research with human subjects. The document contains chapters on common regulatory issues in collaborative research – defines what activities are covered, addresses liability in case of injury to a subject, sharing of data, and harmonizing the informed consent documents. It also includes frequently asked questions and answers. The report also contains a list of national references and website links that would be useful to the TTCP researcher seeking further detail.

The document points to the need for continuing vigilance regarding emerging changes in the policies or legal frameworks of the five nations.

Although this document concludes the work of AG25 at this time, the AG can be reconstituted by the HUM Group Executive Chair to address other human subject research matters or to assist TTCP researchers.



1. INTRODUCTION

The purpose of TTCP is to facilitate the collaboration between member nations regarding defence science and technology. When the collaborative activity includes research involving human subjects, the study review and approval process can become complicated due to different national policies. Action Group (AG) 25 endeavored to understand how each nation's policies could impact the diversity of TTCP research activities. While it is beyond the authority of the HUM Group, AG25 or TTCP to harmonize the different national policies on the protection of human subjects in research, the AG sought to identify the common and unique requirements of each nation.

The TTCP Memorandum of Understanding (MOU), the authority for collaboration amongst TTCP nations, enables the Participants to “cooperate in a broad range of defence S&T activities...” (Section II, Objectives). Section II of the MOU lists the exchange of information as a specific objective. The section ends by stating that “the activities of the Participants ...will be carried out consistent with their national laws.” Therefore, TTCP collaborations do not have special authority to disregard their national laws and policies.

There are many forms of collaboration: exchanging information, equipment, researchers, and even subjects. TTCP 201 (formerly known as “Policies, Organisation and Procedures in Non-Atomic Military Research and Development – POPNAMRAD) outlines the processes for establishing Project Agreements and confidentiality agreements for information exchanges. However, these templates do not address the regulatory requirements regarding human subject research. This report supplements the MOU and TTCP 201 by providing information useful to TTCP researchers when planning collaborative research.

This document identifies and summarizes the major National, Department of Defense (DoD), Department of National Defence (DND), and Ministry of Defence (MoD) policies that researchers must follow to have a compliant human subject research protocol. Researchers who are unfamiliar with conducting human subject research should begin by reading [Chapter 2](#) in order to understand their national policies for protecting human subjects. The report continues with chapters on common regulatory issues in collaborative research.

[Chapter 3](#) describes the activities which constitute “human subject research” and are covered under a nation's policies, and require ethics board approval. An activity is not necessarily human subject research covered by a national policy just because it involves a human being, or the goal is to learn something in an organized manner. Conversely, just because an activity involves military or civilians “doing their job,” the activity is not necessarily excluded from review requirements and ethics board approval.

Each TTCP nation has policies to ensure risk to the subjects is minimized and [Chapter 4](#) outlines each nation's policies regarding liability for providing care and compensation to a subject for research-related injury. In spite of following all of the requirements, adverse events can occur that harm a subject. Although there are many similarities, the national policies are not the same across the member nations and are not always straightforward. TTCP policies also address liability.



Collaboration involving sharing and using existing data is becoming more commonplace. In [Chapter 5](#), each nation identifies and discusses relevant policies covering a variety of human subject research. Sensitivity for protecting a person's information and respecting a subject's right to volunteer are key considerations in sharing and using existing data. Each nation has identified characteristics of the data, that when present, require ethics review (e.g., identifiable data, data collected for research purposes). The types of data requiring review are fairly consistent among the nations.

Another form of collaboration occurs when jointly conducting a study using subjects from multiple nations. In addition to addressing the requirements for liability and data sharing, each nation has to ensure that the common requirement for fully informed and voluntary consent is achieved. [Chapter 6](#) discusses each nation's requirements in the informed consent documents. Although the requirement is common and based on the same ethical standards, the implementation details differ among nations. This can result in each nation, and even organisations within a nation, having their own consent document. [Table 6-1](#) identifies each nation's required elements of informed consent and suggests the common language that should be acceptable to each nation.

[Chapter 7](#) contains a set of Frequently Asked Questions (FAQ) to assist TTCP researchers in understanding the requirements and process for ethical review of human subject research. The FAQ identifies the primary offices in each nation to contact for assistance. The key to an efficient ethics review for collaborative research is early involvement of each nation's approving office. The approving offices can work together to help identify a logical process for research approval, agree to common elements of the protocol and consent material, use appendices to include unique national information thereby maximizing common elements of the protocol and consent material, identify a lead country (if applicable), share a scientific review, etc.

[Chapter 8](#) provides HUM Group's conclusion regarding the need for continuing vigilance on human subjects protection policies in order to support continued efficient collaboration amongst the nations.

[Chapter 9](#) lists all of the relevant national policies regarding human subject research. The reference titles are hyperlinked to the actual document on the world-wide web where applicable.

TTCP researchers should also be aware that it is intrinsic to an ethics review for the review panel to consider the rationale and design of the research project. Many ethics boards associate the quality of the project's science as a reflection on the quality of the ethics of the project itself.

2. NATIONAL POLICY FRAMEWORK FOR RESEARCH INVOLVING HUMAN SUBJECTS

Each TTCP nation has its own framework for legal and national policies for the ethical treatment of human subjects in research. Although there is no standard policy adopted by all five nations, each nation has policies regarding two ethical concerns: human rights and the privacy and confidentiality of individual information. These policies shape the implementing regulations of the national defence organisation and their civilian research organisations. The authority to



create defence-level policy often originates at the national level. Additionally, defence and civilian researchers are often bound by the ethical standards established by their professional societies. Every TTCP researcher should be familiar with their national and defence policies. If a researcher is going to be involved in research conducted in another nation, the researcher should also be familiar with the policies of the host nation.

Tables 2-1 through 2-5 list six levels in the policy framework for research involving human subjects for each TTCP nation. Following is a description of the columns of the tables:

Column 1, “Legal Framework,” lists the national laws and acts relevant to human subject research. These legislative elements primarily concern privacy, human rights, health/medicine, safety, and compensation. The documents in this column provide the legal basis for national and defence policies.

Column 2, “National Policy,” identifies councils, policies, statements, reports, guidelines, etc., that may not have the force of law but implement the legal documents in Column 1.

Column 3, “Defence,” identifies legally enforceable, defence directives and instructions that investigators must comply with when conducting human research.

Column 4, “Defence Research Organisation,” refers to the organisation(s) within the DoD/DND/MoD that are involved with human research. This column identifies the specific DoD/DND/MoD institution guidelines for conducting human research that investigators must use to comply with their DoD/DND/MoD references in Column 3.

Column 5, “Other Government Research Organisations,” cites the references used by non-defence government organisations regarding human research. These citations may or may not be included in Column 3, Defence. References in this column are important when the TTCP collaboration includes government organizations other than Defence.

Column 6, “Non-Government Organisations,” lists the policies followed by institutions such as universities, hospitals, companies, etc. References in this column are important when the TTCP collaboration includes non-government organisations.

2.1. National Policy Framework for Australia

Table 2-1 lists the Australian (AS) framework for research involving human subjects. At the national level there is a set of legislative requirements, covered through the Defence Act 1903; the Public Service Act 1999; the Occupational Health and Safety (OH&S) Act 1991; the Safety, Rehabilitation and Compensation (SRC) Act 1988; and the Privacy Act 1988. The primary national document on ethics in human research is the National Statement on Ethical Conduct in Human Research (hereafter referred to as the National Statement), developed by the National Health and Medical Research Council (NHMRC), in collaboration with the Australian Vice-Chancellors’ Committee and the Australian Research Council (ARC), and published in 2007. The NHMRC is a statutory body established under the National Health and Medical Research Council (NHMRC) Act 1992 and is required to issue human research guidelines. The National Statement is Australia's primary source of guidance for the conduct of all research that involves



human participants. It provides a statement of ethical principles, and serves as a national reference point for ethical consideration relevant to all research involving humans. It defines research as "a systematic investigation to establish facts, principles or knowledge or a study of matter with the objective of obtaining or confirming knowledge."

Through the Defence Act 1903 and the Public Service Act 1999 both uniformed and civilian members of the Defence Department are bound by Defence Instructions (DI). DI(G)-ADMIN 24-3 establishes the Australian Defence Human Research Ethics Committee (ADHREC). ADHREC is a Human Research Ethics Committee (HREC) operating in accord with the National Statement. Human research in this context could include health, human performance, psychology, personnel and equipment trials research. Under the National Statement the level of review is dependent on the level of risk to the human in that research. If the level of risk is more than "low" then the ethical review must be undertaken by a properly constituted Human Research Ethics Committee. ADHREC is such a committee. The Defence Science and Technology Organisation (DSTO) operates an internal ethical review process that initially assesses whether protocols submitted to it carry more than a risk of discomfort (i.e. low risk), and if so refer them to ADHREC. Protocols assessed as dealing with no more than low risk are assessed for ethical conformance by an internal committee chaired by a member of ADHREC and reporting periodically to ADHREC on protocols reviewed. This is in accord with national practice in public research institutions and NHMRC guidelines.

The matter of when ethical review is needed is dealt with in a "level-of-risk" framework. This consists of two parts – an impact component (inconvenience, discomfort, harm), and severity component. A concept of negligible risk is invoked and research that is assessed to have negligible risk does not require review by a formally recognized HREC, but the review must be carried out by people who are familiar with the National Statement and operate in conformance with it (National Statement, paragraphs 5.1.18–21). Higher risk level research must be referred to a properly constituted HREC (National Statement, paragraphs 5.1.24–25).



Table 2-1. National Policy Framework for Australia

Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Declaration of Helsinki Privacy Act 1988 (together with amendments) particularly section 95. Defence Act 1903 , section 9A (this provides the legal basis for Defence Instructions (see Column 3)) Public Service Act 1999 (provides the legislative basis for legally enforceable directions applicable to public servants) Safety, Rehabilitation and Compensation Act 1988 (and amendments) Occupational Health and Safety Act 1991	National Health and Medical Research Council - this is a statutory body established by legislation (NHMRC Act 1992) - Sect 8(1) requires NHMRC to issue guidelines. The NHMRC issues the National Statement on Ethical Conduct in Human Research , which is sponsored by Minister for Health and Ageing. It is developed jointly by the NHMRC, the Australian Research Council, and the Australian Vice-Chancellors' Committee. The Australian Research Council Act 2001 established the ARC to provide advice to The Minister for Health and Ageing re. financial assistance to research programs.	DI(G)s are legally enforceable where word "must" is used. DI(G) ADMIN 0-0-001 The System of Defence Instructions DI(G) ADMIN 24-3 Conduct of Human Research in Defence establishes ADHREC as the body which provides ethics approval, in accordance with NHMRC requirements, for research which is more than low risk. Its members are appointed by the Minister for Defence -ADFP 1.2.5.3 DI(G) PERS 16-20 Privacy of health information in Defence governs the use of Defence personnel's health information, including the use of health information for research purposes.	Chief Defence Scientist Instruction, CDSI (under review), (establishing internal ethical review requirement and procedures, under ADHREC oversight) DSTO draft policy of clarification (SOP like Under Chief Defence Scientist Applies to all HSR; does scientific review and feeds into ADHREC as required)	NHMRC National Statement Public Service Act Privacy Act SRC Act OH&S Act	Australian Code for the responsible conduct of research Revision of Joint NHMRC/ Australian Vice-Chancellors' Committee (AVCC) Statement and Guidelines on Research Practice (1997) NHMRC National Statement Public Service Act Privacy Act SRC Act OH&S Act



2.2. National Policy Framework for Canada

Table 2-2 identifies the Canadian policy framework for conducting research involving human participants (subjects), with particular emphasis placed on research conducted for and by the DND. At the topmost level is the Legal Framework (Column 1) that identifies the Federal Acts and associated relevant regulations which impact on the environment for conducting human research in Canada. Foremost here are the Acts that address privacy protection of personal information, human rights to mitigate discriminatory and inequality practices, conducting ethical and quality health research, all matters relating to DND and the Canadian Forces including research issues, on-job injury compensation, and employee safety codes. These are further discussed at <http://laws.justice.gc.ca/en/>.

National Policy (Column 2) in Canada is dictated largely by the requirements imposed by the National Council on Ethics In Human Research (NCEHR) through their Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) – see <http://www.pre.ethics.gc.ca>. The TCPS describes standards and procedures governing research involving human participants that must be complied with by individuals and institutions receiving funding for human sciences research from Canada's three Granting Agencies. Plans are afoot to develop a publicly accountable governance framework, including an accreditation and certification program that will mandate all Canadian Research Ethics Boards (REBs) to adhere to the ethical standards of the TCPS. The issue of protecting privacy and confidentiality is also being addressed from both health sciences, and social and behavioural sciences view points.

Defence (Column 3) identifies the Defence Administrative Orders and Directives that set forth DND's policy (DAOD 5061-0) and procedures (DAOD 5061-1) that define the requirements, conditions, and restrictions for conducting research involving human participants – see http://www.admfincs.forces.gc.ca/admfincs/subjects/daod/5061/0_e.asp. Foremost herein is the necessity for establishing institutional REBs that review all human research projects and also conduct themselves otherwise in accordance with these DAODs and the standards imposed in the TCPS. Furthermore, Canadian Forces General Order (CANFORGEN) 198/08 addresses the issues of quality control and coordination for conducting survey research within DND – see http://vcds.dwan.dnd.ca/vcds-exec/pubs/canforgen/2008/198-08_e.asp.

Defence Research Organisation (Column 4) refers to the Guidelines that DND complies with for its in-house human sciences research; these adhere to the requirements laid down in the two DAODs and the TCPS. In addressing all contract human science research conducted for DND by external agencies, these guidelines stipulate that such research must be reviewed and approved by internal Human Research Ethics Committee, even in those instances where the institutions have approved the research by their own REB.

Other Government Research Organisations (Column 5) and Non-Government Organisations (Column 6) in Canada must comply with the TCPS.



Table 2-2. National Policy Framework for Canada

Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Privacy Act Canadian Human Rights Act Canadian Charter Rights & Freedoms S.7 (life, liberty & security of person) S.15 (equality & discrimination) Canadian Institutes of Health Research (CIHR) Act C.6 2000 National Defence Act Government Employees Compensation Act Canada Labour Code, Part II	NCEHR Tri-Council Policy Statement (TCPS) Health Canada wants a program of accreditation to cover all Canadian REBs NCEHR Task Force: report on accreditation system development CIHR Sept 05: report on best practices for protecting privacy in health research Tri-Council Advisory Panel: draft report re: privacy & confidentiality for social and behavioral sciences	DAOD 5061-0 (policy) DAOD 5061-1 (procedures) CANFORGEN 198/08 All three under Chief of Medical Personnel (CMP) who delegates authority to DRDC and Surgeon General DND adopts TCPS	DRDC S&T uses DRDC Guidelines signed by ADM S&T (governing research body) (centralized for all labs) DRDC CORA has own set of guidelines under CMP Applies to all HSR DRDC “approved by TCPS” Surgeon General adopts the DAODs	TCPS	TCPS for hospital, university, etc. HSR funded by Tri-Council grants

2.3. National Policy Framework for New Zealand

Table 2-3 lists the New Zealand (NZ) policy framework for research involving human subjects. Seven acts form the basis of legislation pertaining to research involving human subjects. The Health and Safety in Employment (HSE) Act (1992) outlines the duties of employers and employees to ensure all practicable steps are taken to maintain safe working conditions. Part two of the act, General Duties of Employees, outlines the responsibility of employers. As a result of this act, it is the responsibility of the New Zealand Defence Force (NZDF) to ensure that all practical steps are taken to ensure that personnel involved in research are working in safe conditions. The purpose of the Injury Prevention Rehabilitation Compensation Act (2001) is to provide a fair and sustainable scheme for managing personal injury. Part two, section 28 defines work related injury, if as a result of any research, an individual should be injured, they would be



compensated through this act. The Privacy Act (1993) outlines the provisions for collecting, storing, access to, use and disclosure of personal information. Part two, section six outlines the information privacy principles. This section should be reviewed prior to conducting research. The Official Information Act (1982) provides guidance for the access to and protection of official information, which includes information collected and produced as part of research. In particular part four, section 24 outlines rights of access to personal information. The Health Practitioners Competence Assurance Act (2003) aims to protect the public by ensuring the competence of professionals including psychologists, doctors and nurses. The Human Rights Act (1993) outlines the prohibited grounds for discrimination of persons. For medical research the Declaration of Helsinki (1964) provides guidance on how Biomedical Research, Medical Research Combined with Professional Care and Non-Therapeutic Biomedical Research involving human subjects should be conducted.

Table 2-3. National Policy Framework for New Zealand

Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Health & Safety in Employment Act 1992 Injury Prevention, Rehabilitation and Compensation Act 2001 Privacy Act 1993 Official Information Act 1982 Health Practitioners Competence Assurance Act 2003 Human Rights Act 1993 Declaration of Helsinki	<p>Within NZ, there is no national policy for research with human subjects. In reality the agency conducting is bound by a relevant ethics committee (e.g., national health ethics committee, regional health ethics committee and university ethics committee).</p>	<p>NZDF has DFO (Defence Force order) 21/2002 Authority to conduct Personnel Research</p> <p>NZDF medical research requires NZ Medical Ethics Committee approval and may need legal review</p>	<p>Defence Technology Agency (DTA), Assistant Chief of Personnel (AC Pers) and single Service's.</p> <p>Director General Medical Services (DGMS)</p>	<p>Social Policy Evaluation & Research (SPEaR) group comprised of public service dept members and promote and develop ethical guidelines for research within government.</p>	<p>Research conducted in partnership in reference to various code of ethics and ethics committees including the Association of Social Science Researchers (ASSR) and Australasian Evaluation Society (AES)</p>



2.4. National Policy Framework for the United Kingdom

Instructions for the ethical conduct and treatment of human participants in all MoD research, and the process of assessment of research protocols, are provided in a Joint Services Publication (JSP 536). This was produced in 2005 when it was recognized that all research involving human participants relating to the responsibilities of the Secretary of State for Defence must be subject to ethical scrutiny by the MoD Research Ethics Committee (MoDREC).

All MoD funded research involving human volunteers (and non-MoD funded work on military personnel) must therefore comply with JSP 536 and submit an ethical protocol to the MoDREC for approval. Scientific peer review is initially undertaken by one of four MoD Scientific Advisory Panels, comprising a pool of people with expertise in disciplines such as physiology, psychology, and clinical medicine. Once approved, the proposal is passed to one of two parts of MoDREC: MoDREC (General) or MoDREC (Personnel, Protection and Effectiveness). The latter focuses primarily on specialised research conducted in the area of Chemical, Biological and Radiological and Nuclear Defence. Both committees include independent, external expert and lay members who bring with them a wealth of information from different fields.

Investigators may also need to submit their protocol separately to a National Health Service (NHS) Local Research Ethics Committee (LREC), if it involves any of the following:

- a. Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient's or user's past or present treatment by the NHS.
- b. Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS.
- c. Access to data, organs and other bodily material of past and present NHS patients.
- d. The use of NHS premises or facilities.
- e. NHS staff recruited as research participants by virtue of their professional role.

In the case of a multicentre study (i.e. involving several research sites), Multicentre Research Ethics Committee (MREC) approval may be necessary.

To bring some order to and to help streamline the ethical review process within the NHS, the British government established the Central Office for NHS Research Ethics Committees (COREC), recently renamed the National Research Ethics Service (NRES). COREC instigated a central set of instructions to harmonise the Research Ethics Committee (REC) approach to applications. It provides guidelines on operating procedures for LRECs and MRECs.

In addition, MoD must comply with the document "Safety, Health and Environmental Protection in the MoD" (JSP 375) and all relevant health and safety legislation to provide working conditions that will ensure, as far as possible, a healthy and safe working environment. Health and Safety criteria apply to all aspects of research and to both investigators and participants.

At a national level, the British Psychological Society (BPS) identified a need to give support to the process of ethical decision-making, and in 2006 produced a Code of Ethics and Conduct. This Code provides the parameters within which professional judgements should be made.



MoDREC ensures that protocols submitted for approval abide by the guidelines given in JSP 536. The JSP 536 is the key document which provides guidance on required ethical standards for MoD research. It is based on national and international accepted practices and guidance, described in Appendix 1.

Table 2-4. National Policy Framework for the United Kingdom

Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Declaration of Helsinki Originally Adopted 1964 The Medicines of Human Use (clinical trials) Regulations 2004 Data Protection Act 1998 Human Rights Act 1998 Census (Confidentiality) Act 1991 Access to Health Records Act 1990 Health and Safety at Work Act 1974 Human Tissue Act 2004 Freedom of Information Act	Psychological research must comply with guidelines set out by the British Psychological Society – Code of Conduct March 2006	JSP 536 (a joint services publication which all MOD funded work must abide by) The MoD Health and Safety Handbook, JSP 375	All MoD research organisations (e.g. ARTD, RAFCAM, INM and Dstl) must abide by JSP536 and submit protocols to MODREC(Gen) or MODREC(PPE)	NRES provides the guidelines for ethical procedures for the NHS.	Academic Institutions and other non-government organisations (e.g. QinetiQ) have their own individual ethics policies and guidelines, however when participating in MOD funded research they must also abide by the JSP guidelines.

2.5. National Policy Framework for the United States

Table 2-5 lists the United States (US) policy framework for research involving human subjects. The framework is based on two federal regulations. The first federal regulation is the “Federal Protection for the Protection of Human Subjects in Research.” This policy applies to nearly all federally sponsored or conducted human subject research. Eighteen federal departments and agencies either have codified the same policy in their own section of the Code of Federal Regulations (CFR) or have required compliance with this “Common Rule” through another internal regulation. DoD codified the Common Rule in 32 CFR Part 219 (32 CFR 219). Among other things, this policy defines human subject research, outlines the basic principals research institutions must follow, lists basic requirements the informed consent process, and defines the composition and responsibilities of an Institutional Review Board (IRB). DoD researchers



should pay close attention to the following sections of the policy: the scope and definitions; the requirement for the researcher's institution to have a federal assurance, criteria for IRB review of the research protocol, and the required elements of informed consent.

The second federal regulation has been codified by the Food and Drug Administration (FDA). This set of regulations is applicable when the research involves drugs, biologics, or medical devices. The principal FDA regulations are found in 21 CFR Parts 50, 56, 312, 600, and 812. Some of the requirements overlap with the Common Rule.

In addition to the two national regulations, the DoD has a unique requirement in 10 United States Code 980 (10 USC 980). Briefly stated, this policy requires DoD funded research to obtain informed consent from a subject unless a waiver of informed consent is approved by the Secretary of Defense. This authority has been delegated to the Heads of each DoD Component. The Privacy Act of 1974 addresses how and when personal information collected by a federal agency can be released. The Health Insurance Portability and Accountability Act (HIPAA) addresses access to and release of private health information.

The DoD implements 32 CFR 219 through DoD Directive 3216.02 (DoDD 3216.02). In the directive, the Secretary of Defense has delegated the authorities and responsibilities outlined in 32 CFR 219 to the Director of Defense Research and Engineering (DDR&E). The directive outlines additional requirements and delegates authorities to the heads of the DoD Components. There are other DoD regulations for research involving drugs (DoD Instruction 6200.02), medical treatment funding (DoD Instruction 6000.8), private health information covered by HIPAA (DoD 8580.02-R) and surveys of DoD personnel (DoD Instruction 1100.13).

The Defense Research Organizations within the DoD have organizational level policies and procedures to implement DoDD 3216.02. As of 2008, there are 11 DoD Components that sponsor and/or conduct human subject research. A list and web links to the DoD Components can be found at <http://www.dtic.mil/biosys/org/hu.html>. The DoD Component policies and procedures outline such topics as additional protections for human subjects, unique issues of recruiting military as subjects, and requirements for research institutions, Institutional Review Boards, research protocols, and the informed consent process. When collaborating, the researchers are strongly encouraged to contact their DoD Component headquarters oversight office (e.g., their Office of the Surgeon General or Director of Research). This office can often assist in supporting economies of review and facilitating research approval if they are involved during the development of the research protocol.

Numerous federal departments and agencies follow the same Federal Policy for the Protection of Human Subjects (i.e., the Common Rule). A list of these government organizations can be found at <http://www.dtic.mil/biosys/org/hu.html>. Each government organization has the authority to interpret the federal policy and develop additional regulations and guidance. The DoD Component headquarters oversight office can assist the researchers in contacting the appropriate offices in other government organizations when necessary.

Non-government organizations are required to follow the Federal Policy for the Protection of Human Subjects when a federal department or agency is sponsoring the research. If there is no



federal government sponsor, the non-government organizations may at their discretion choose to apply the federal policy to their research. Additionally, there are professional societies that have developed their own code of conduct or have endorsed the federal standards.

Table 2-5. National Policy Framework for the United States

Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
32 Code of Federal Regulations, Part 219 (32 CFR 219) Where applicable the Food and Drug Administration policies (e.g., 21 CFR Parts 50, 56, 312, 600, and 812) Title 10 United States Code Section 980 (10 USC 980) Privacy Act of 1974 , Section 522a of Title 5, United States Code (5 USC 522a) and Public Law 93-579 Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191 and 45 Code of Federal Regulations Parts 160,162, and 164 (45 CFR 160, 162, and 164)	32 Code of Federal Regulations, Part 219 (32 CFR 219) Where applicable the Food and Drug Administration policies (e.g., 21 CFR Parts 50, 56, 312, 600, and 812) Title 10 United States Code Section 980 (10 USC 980) Privacy Act of 1974 , Section 522a of Title 5, United States Code (5 USC 522a) and Public Law 93-579 Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191 and 45 Code of Federal Regulations Parts 160,162, and 164 (45 CFR 160, 162, and 164)	DoDD 3216.02 DoD Instruction 6200.02 DoD 8580.02-R DoD Instruction 6000.8 DoD Instruction 1100.13	Each of the 11 DoD Components conducting or sponsoring human subject research have implementing policies and procedures (e.g., Army Regulation 70-25 ; Secretary of Navy Instruction 3900.39D (SECNAVINST 3900.39D); Air Force Instruction 40-402)	Each federal agency (e.g., Dept of Health and Human Services) has the same language as 32 CFR 219 in their title of the CFR (e.g., DHHS is at 45 CFR 46)	Follows the Federal Policy (e.g., 32 CFR 219 or 45 CFR 46) when research is sponsored by a federal agency Some professional societies have developed a code of conduct

3. NATIONAL POLICY FRAMEWORK REGARDING THE DEFINITION OF HUMAN RESEARCH

Each nation has a national policy framework that establishes parameters for the types of activities that are covered by their human research policies. Often, covered activities encompass



more than research, and may include development, test, evaluation, and even training. All of these kinds of activities are collectively referred to as “research” in this document and in most national policies.

The word research is defined by the Cambridge Advanced Learner’s Dictionary as “a detailed study of a subject, especially in order to discover (new) information or reach a (new) understanding.” Many TTCP collaborative activities can fit this broad definition. The national policies regarding human research are not intended to apply to all activities involving human beings and resulting in new information. By calling an activity “research,” the national policies do not necessarily apply; the activity has to meet the policy definition or the criteria. Conversely, calling an activity something other than research does not mean that the research policies do not apply. It is the purpose of the activity that is held up to the national policy to determine if the activity is covered. Most research has a human being involved in some fashion. They can be the object of the research (e.g., analysis of their blood, survey of their lifestyle, etc.) or an indirect object of research (e.g., the driver of a tank being tested for maneuverability). Close attention should be given to the criteria used to determine if a person is considered a subject of the research. These determinations can be very complicated and should be made by an experienced person authorized by the organisation (and not the person conducting the activity).

Tables 3-1 through 3-5 below list each nation’s policies that define the criteria for what activities are considered research involving human subjects. The list of policies also outlines any unique requirements for conducting this type of human research.

[Table 3-6](#) identifies some but not all of the common TTCP collaborations likely be considered human research and covered under each nation’s human research policies. Table 3-6 shows some of the differences among nations in defining what activities are most likely considered human research and require ethics approval. The variations can result in one nation determining an activity to be covered and require the approval of the ethics board and another nation determining the same study to not be covered under the national policies and therefore does not need ethics board approval. As long as a study is conducted in accordance with the national policies of the researcher, the collaborating nations should accept the ethical determinations of the other nations and allow the TTCP researchers to collaborate. See [Chapter 5](#) for more information about collaboration.

3.1. National Policy Framework Regarding the Definition of Research for Australia

The primary document for ethical review in Australia is the National Statement. This document does not focus on the definition of research per se but on:

- a. what is human research?
- b. when and by what means does human research, or other activities such as quality assurance or improvement, or clinical audit, need ethical review?

The National Statement states that “human research is conducted with or about people, or their data or tissue”. Then notes that the following forms of participation are included in human research for the purposes of ethical consideration:



- taking part in a survey, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to participant's documents or other materials;
- the collection and use of participant's body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath; or
- access to participant's information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing or unpublished source or database.

Additionally the National Statement notes that a broad sense of what constitutes a participant in human research is taken, allowing for cases in which participants are unaware of the fact that they are the subjects of the research. It also notes that non-participants may be impacted by the research and if this is reasonably foreseeable then the research may raise ethical issues because of the nature of this impact.

For the Australian Defence Department DI(G) ADMIN 24-3 provides a definition of research (paragraph 4) and notes that human research could include health, human performance, psychology, personnel and equipment trials research. Each of these are detailed in DI(G) ADMIN 24-3 (paragraphs 5-10).

Table 3-1. National Policy Framework Regarding the Definition of Research for Australia

Research Elements/ Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Federally funded/ conducted	OH&S Act SRC Act Privacy Act	National Statement	DI(G) ADMIN 24-3	CDSI (under review)	National Statement	National Statement
RDT&E	OH&S Act SRC Act Privacy Act	National Statement				
Intervention or interaction with living individuals: -identifiable data (biomedical, physiological, and behavioral/ social) -biological tissues & substances	OH&S Act SRC Act Privacy Act	National Statement	Privacy Act			



Research Elements/ Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Vehicle/ equipment/ clothing evaluation Environmental effects on humans	OH&S Act SRC Act Privacy Act		OH&S Act Conformance required. Health Manual , Vol 23 para 2.14			
New standard operating procedures with acceptable risk	OH&S Act SRC Act Privacy Act					
Cadavers & associated human remains	OH&S Act SRC Act Privacy Act	National Statement				

3.2. National Policy Framework Regarding the Definition of Research for Canada

Table 3-2 identifies the applicable policy framework for the different research elements/types of activity (Column 1) conducted in Canada. For all of the different human research elements/activities sponsored, supported, or conducted by/for DND, DAOD 5061-0 and CANFORGEN 198/08, in conjunction with the TCPS must be applied in drafting research protocols. Additionally, protocols reviewed by the DRDC Human Research Ethics Committee or the Director General Military Personnel Research and Analysis (DGMPPRA) Research Ethics Board must adhere to the DRDC Guidelines for Human Subject Participation in Research Projects or DGMPPRA Guidelines, respectively. Other Government Research Organisations (Column 6) and Non-Government Organisations (Column 7) must comply with the TCPS when federally funded, as well as DND policies and guidelines when undertaking work on behalf of DND/Canadian Forces. TTCP Activities, in regard to research ethics considerations in collaborative projects, could best be addressed in a TTCP MOU Project Arrangement (PA). The TTCP MOU PA needs to stipulate that research ethics review and approval must meet the criteria laid down in the policy frameworks of the respective TTCP collaborators before experiments can commence.



Table 3-2. National Policy Framework Regarding the Definition of Research for Canada

Research Elements/Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Federally funded/conducted	DAOD 5061-0 and CANFORGEN 198/08	TCPS , Government of Canada (GoC) Communications Policy; Treasury Board (TB) Policy On Collection and Storage of Personal Info; TB and Public Works & Government Services Canada (PWGCS) Policy on Public Opinion Research	DAOD 5061-0 and CANFORGEN 198/08	DAOD 5061-0 and CANFORGEN 198/08 DRDC Guidelines TCPS	TCPS Statistics Canada Act	TCPS
RDT&E		Not covered	Not covered	Not covered	Not covered	Not covered
Intervention or interaction with living individuals: -identifiable data (biomedical, physiological, and behavioral/social) -biological tissues & substances	DAOD 5061-0 and CANFORGEN 198/08	TCPS Ss. 1, 3 & 10	DAOD 5061-0 and CANFORGEN 198/08	DAOD 5061-0 and CANFORGEN 198/08 DRDC Guidelines TCPS	TCPS Ss. 1, 3 & 10	TCPS Ss. 1, 3 & 10 if Government funded
Vehicle/ equipment/ clothing evaluation: -environmental effects on humans	DAOD 5061-0	TCPS S. 1	DAOD 5061-0	DAOD 5061-0, DRDC Guidelines, & TCPS	TCPS S. 1	TCPS S. 1 if Government funded
New standard operating procedures with acceptable risk	DAOD 5061-0	Implied in TCPS S. 1	DAOD 5061-0	DAOD 5061-0 Implied in DRDC Guidelines	Implied in TCPS S. 1	Implied in TCPS S. 1 if Government funded
Cadavers & associated human remains	TCPS S.1	TCPS S. 1	Not covered	TCPS S.1	TCPS S.1	TCPS Ss. 1 & 10 if Government funded



Research Elements/Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Exemptions: 1. Routine educational testing 2. Quality assurance studies 3. Strict performance reviews 4. Occupational training 5. Anonymous data extracted from an existing data set or medical specimens 6. Vehicle, equipment, or clothing evaluation other than above	DAOD 5061-0 and CANFORGEN 198/08 TCPS	TCPS S.1 (for 1., 2., 3., 5. in Col. 1)	DAOD 5061-0 and CANFORGEN 198/08 (for 6., 7. in Col. 1)	DRDC Guidelines (for 4., 6., 7. in Col. 1)	TCPS S.1 (for 1., 2., 3., 5. in Col. 1)	TCPS S.1 (for 1., 2., 3., 5. in Col. 1)

3.3. National Policy Framework Regarding the Definition of Research for New Zealand

The Health Practitioners Competence Assurance (HPCA) Act (2003) is part of the New Zealand legal framework which aims to protect the public by ensuring psychologists and medical personnel are competent and fit to practice in their profession. However no specific definition for Research is provided in the Act. For medical research the Declaration of Helsinki (1964) provides guidance for Biomedical Research, Medical Research Combined with Professional Care and Non-Therapeutic Biomedical Research involving Human Subjects (Non-Clinical Biomedical Research). At a national level for psychological research the New Zealand Psychological Society Code of Ethics outlines the provisions that registered psychologists must abide by when conducting research, although research itself is not defined. In particular researchers should review principles 1.6 Privacy and Confidentiality, 1.7 Informed Consent and principle 2.6 the Wellbeing of Human Research Participants.

For Personnel and Psychological Research within the Military, DFO 21/2002 provides the guiding framework for conducting research. This DFO can also apply to medical research. DFO 21/2002 defines personnel research as “any systematic investigation of the behaviour or other psychological attributes (such as attitudes or opinions) of individuals or groups, in so far as they affect the efficiency of the NZDF.” Any research which does not fall under this definition is not required to follow the process outlined in DFO 21/2002.



Table 3-3. National Policy Framework Regarding the Definition of Research for New Zealand

Research Elements/Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Personnel Research		No national ethics review process but determined in partnership with agency conducting the research and relevant ethical approval.	DFO 21/2002	DFO 21/2002		
Psychological Research	HPCA Act	NZ Psych Society Code of Ethics	DFO 21/2002	DFO 21/2002		
Medical Research	Declaration of Helsinki (1964) HPCA Act		Single Service DFOs			

3.4. National Policy Framework Regarding the Definition of Research for the United Kingdom

The United Kingdom (UK) MoD JSP 536 states that ethical consideration should apply to MoD funded/sponsored research carried out on human participants, and also any non-MoD research involving military personnel. The guidelines apply to any project in which the researchers:

- Conduct experiments upon the human participant (i.e. conduct research rather than treatment); including (but not limited to) administering substances, taking blood or urine samples, removing biological tissue, radiological investigations, or obtaining responses to an imposed stress or experimental situation
- Conduct experiments to collect data on an identifiable individual's behaviour, either directly or indirectly (such as by questionnaire or observation).
- For the purpose of research, use non-public domain records and papers that contain information that is private or personal and could identify an individual (or group of people) and could cause harm.

There are a number of exceptions where these rules do not apply:

- Military operations, unless a research data gathering element is involved.
- Training and exercises, unless a research data gathering element is involved.



- c. Personnel who are testing or evaluating vehicles, equipment or materials, (e.g. experienced personnel assessing operability of commercially manufactured equipment that has established safety standards) unless the purpose is to determine the effect of an item on the human participant as part of a research project.
- d. Studies of new features or techniques during training or field operations following standard operating procedures in which the risk or stress to personnel does not exceed in any manner that which is inherent in the participant's daily life, occupation or field of service.
- e. Personnel carrying out standard operating procedures, undergoing acceptable, occupational training techniques (e.g. military pilots taking centrifuge training). However, experiments on protection involving centrifuge research on humans would require ethical approval even though both activities involve riding the human centrifuge.
- f. Epidemiological or retrospective studies employing secondary data from the public domain or obtained for purposes other than research where the use of such items cannot be linked, or cannot cause harm or distress, to an individual or group of individuals.
- g. Cases where ethical oversight is a matter of course (e.g. where an MoD employee is a volunteer in a clinical research project at an NHS hospital), or where an MoD employee is acting in an entirely personal capacity.

Table 3-4. National Policy Framework Regarding the Definition of Research for the United Kingdom

Research Elements/ Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Personnel	Declaration of Helsinki Data Protection Act 1998 Human Rights Act 1998 Census (Confidentiality) Act 1991 Health and Safety at Work Act 1974		Research is defined in the JSP 536 as “undertaking a research project involving investigations on human participants”	JSP 536		JSP 536 when undertaking work for MoD



Research Elements/ Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Psychological	Declaration of Helsinki Data Protection Act 1998 Human Rights Act 1998 Census (Confidentiality) Act 1991 Health and Safety at Work Act 1974	BPS Code of Ethics and Conduct . The definition of ethics as the science of morals or rules of behaviour overlaps with the definition of psychology as the scientific study of internal and external behaviour	Research is defined in the JSP 536 as “undertaking a research project involving investigations on human participants”	JSP 536		JSP 536 when undertaking work for MoD
Medical	Declaration of Helsinki Data Protection Act 1998 Human Rights Act 1998 Census (Confidentiality) Act 1991 Health and Safety at Work Act 1974 The Medicines for Human Use (clinical trials) Regulations 2004 Access to Health Records Act 1990 Human Tissue Act 2004 (parts of the act which relate to research came into force in 2006)		Research is defined in the JSP 536 as “undertaking a research project involving investigations on human participants”	JSP 536 NRES	NRES State that “the primary aim of research is to derive new knowledge, including studies that aim to generate hypotheses, as well as studies that aim to test them”. As research may carry greater risk to good clinical practice and may generate conflicts of interest for the healthcare professional it warrants mandated ethical review. Ref: Defining Research www.nres.npa.nhs.uk	JSP 536 when undertaking work for MoD NRES

3.5. National Policy Framework Regarding the Definition of Research for the United States

The US national policy, 32 CFR 219, has a section that defines the two terms “research” and “human subject” and describes six categories of human subject research that are exempt from the policy (e.g., required ethics review). The two key definitions are cited at 32 CFR 219.102. Paragraph (d) defines research to mean “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Paragraph (f) defines human subject to mean:



a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venepuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

The national policy does not require all activities that meet the definitions of research and human subject to comply with the provisions of the policy. Some activities involve so little risk that the required process would result in little value added to ensure the ethical treatment and safety of the subject. Criteria or a description of activities that are exempt from the federal policy and IRB review are listed at 32 CFR 219.101(b). The section lists six types of human subject research that are exempt from review. Three exemption categories are commonly used and are described as follows:

- (b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:
 - (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and,
 - (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation....
 - (3) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.



The following table lists the national policy that defines when an institution is engaged in research involving human subjects. DoD Directive 3216.02 supports the national policy and does not provide further guidance about the definitions of human subject and research. Each of the DoD Component policies also support the standard definitions.

Table 3-5. National Policy Framework Regarding the Definition of Research for the United States

Research Elements/ Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Federally funded/ conducted	32 CFR 219.101	32 CFR 219.101	DoDD 3216.02 (no additional guidance)	DoD Components' policies implement stated definition	32 CFR 219.101 (or its equivalent policy)	none
RDT&E	32 CFR 219.102(d)	32 CFR 219.102(d)		DoD Components' policies implement memo; some are more restrictive (i.e., do not support all of the non-applicable categories)	32 CFR 219.102(d) (or its equivalent policy)	none
Intervention or interaction with living individual (includes identifiable data, tissues, and anatomical substances)	32 CFR 219.102(f)(2)	32 CFR 219.102(f)(2)	DoDD 3216.02 (no additional guidance)	DoD Components' policies implement stated definition	32 CFR 219.102(f)(2) (or its equivalent policy)	none
Not cover cadavers		32 CFR 219.102(f)	DoDD 3216.02 (no additional guidance)	DoD Components' policies implement stated definition	32 CFR 219.102(f) (or its equivalent policy)	none



Research Elements/ Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Some Exemptions: 1. Routine educational testing 2. Anonymous surveys 3. Identifiable surveys with “no” risk from disclosure 4. Data recorded anonymously from an existing data set		32 CFR 219.101(b)	DoDD 3216.02 (no additional guidance)	DoD Components’ policies implement stated definition	32 CFR 219.101(b) (or its equivalent policy)	none

3.6. Comparison of the Scope of the Definition of Research

Sections 3.1–3.5 of this chapter explain each nation’s criteria for applying their human subject policies to the activities that include a human being (or their information) and where the goal is to systematically establish facts. Not all activities that answer a question and involve human beings are covered by the national human subject research policies and require approval by an ethics board. For example, most TTCP nations do not consider the collection of information about providing standard medical care, conducting military operations, or conducting training to be covered under the national human research policies. There is a two-pronged test to determine if the proposed activity involving a human is covered: why are you doing the activity (i.e., is the purpose of the activity research) and what are you doing (i.e., is the kind of intervention or interaction with the human a covered activity).

The activities listed in Table 3-6 below illustrate the diversity of TTCP activities that may or may not be considered “research” or involve “human subjects.” Activities that most likely would be considered human research are indicated by a √, and activities that probably would not be considered to be human research are indicated by an X. These are just a few examples; a modification to the examples that changes the intent or the nature of the involvement of the human could change the determination of “covered” or “not covered.”

Table 3-6. Some Common Activities That May or May Not Be Considered Human Subject Research

Activity	AS	CA	NZ	UK	US
1. Administering substances	√	√	√	√	√
2. Taking blood or urine samples for research	√	√	√	√	√



Activity	AS	CA	NZ	UK	US
3. Removing biological tissue for research	√	√	√	√	√
4. Radiological investigations for research	√	√	√	√	√
5. Collecting physiological data for research	√	√	√	√	√
6. Medical evaluations, investigations or treatments that are <u>not</u> the standard of care	√ 1	√	√	√	√
7. Collection of data on an individual's behaviour (such as questionnaires, surveys and observation by such means as video recording, web-based responses, telephone interviewing, etc.)	√	√	√ 2	√	√ 3
8. Collecting data about public individuals based exclusively on publicly available information or observations	X	X	√	X	X
9. Collecting data about military operations*	X	X	X	X	X
10. Collecting data about training or exercises*	X	X	X	X	X
11. Collecting data about vehicles, equipment or materials that have established safety standards (operators are experienced personnel)*	X	X	X	X	√ 4
12. Collecting data about new techniques or features during field operations or training that follows standard operating procedures, and in which the risk or stress to personnel does not exceed that which is inherent in the individual's daily life (data collection may include personal information about the personnel involved in the training).	X 5	X 6	X 2	X	√ 4
13. Collecting data about standard operating procedures (including the personnel conducting the SOPs) *	X	X	X	X	X
14. Simulations conducted for research (there may or may not also be a training element)	√	√	√	√	√
15. Occupational training*	X	X	X	X	X
16. Routine educational testing*	X	X	X	X	X 7
17. Conducting research using data from existing non-identifiable records	X 8	X	√ 9	√	X
18. Conducting research using data from existing identifiable records	√ 8	√	√ 9	√	√ 10
19. Food and nutrition research	√	√ 11	√ 12	√	√ 13
20. Quality assurance studies	X 14	X	X	X	X
21. Performance reviews*	X	X	X	X	X
22. Research involving human remains	√	√	√ 15	√	X

* The conduct and evaluation of military operations, training, and military exercises; the testing of equipment and materials; and organisational or individual performance reviews are not considered research unless there is an additional element inserted in activity for the specific purpose of human research.



1. (AS) Conditional response – if systematic investigation then HREC otherwise determined on a case-by-case basis within institution.
2. (NZ) If the assessment is of the technique and is not going to have any impact on the person then it is not personnel research.
3. (US) If the only interaction is a survey, focus group, or observation, if there is no intervention (e.g., change in the individual's environment, blood test, EEG, etc.), and if the interaction is anonymous or a breach of confidentiality would not put the individual in jeopardy, the human subject research may be exempt from ethical approval by the Institutional Review Board.
4. (US) If the activity meets the definition of "human subject" and "research, development, testing, and evaluation" then the experience and job description of the individual is immaterial and the activity requires ethical approval. To meet the definition of "human subject" the purpose of the activity should include learning about the human.
5. (AS) If classified as "low risk", these studies may be handled by locally established review panels in accord with the National Statement on Ethical Conduct in Human Research, otherwise referred through to HREC.
6. (CA) If any part of activity constitutes human research, then ethical approval is required.
7. (US) Human subject research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods would be exempt and would not need ethical approval.
8. (AS) The subject consent form allows for the subject to limit re-use of their data. Hence there is not an absolute coding possible on this condition.
9. (NZ) If the research is for the same purpose for which it was collected, ethical approval was granted and individuals consented, it is research but no new approvals are required. If it is for a different purpose and even if covered by an extant consent then there is still a need to get new approval.
10. (US) Human subject research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects is exempt and does not need ethical approval by the Institutional Review Board.
11. (CA) Research ethics protocol review is required if the studies are on the effects of food/nutrition on the human participant, e.g., in diet studies where new food or supplements are tested.
12. (NZ) Currently even consumer acceptance and taste and food quality evaluations, if seeking attitudinal or behavioral responses is considered research and would need approval under DFO 21/2002.
13. (US) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the U.S. Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture are exempt and do not need ethical approval.
14. (AS) Review required in some cases, specifically where there is activity that involves personnel being exposed to conditions at the limits of physiological or psychological integrity.
15. (NZ) Human Tissue Act 2008 covers consent for taking tissue from Human remains.

4. NATIONAL POLICY FRAMEWORK REGARDING RESEARCH LIABILITY

Researchers strive to minimize risks to the subjects. But risk can never be reduced to zero. All research studies have known and unknown risks to the subjects. Each nation requires that the anticipated risks be explained to the subjects during recruitment for the research (see [Chapter 6](#) for more information about informed consent).

Additionally, the consent process must also explain what care will be provided to the subjects who are injured and who will pay the costs of treatment and subsequent care. Each nation has policies outlining compensation for injury. The policies may differ depending on the



employment status of the subjects: military, civil servants, and civilians not employed by the government.

When there is collaboration among TTCP nations, the protocol and consent process need to address the provisions for liability. TTCP 201 (formerly known as “Policies, Organisation and Procedures in Non-Atomic Military Research and Development – POPNAMRAD) states that when collaborating, “each Participant funds its own participation and accepts any risk to its people and equipment” (Section 3.1.4). When each nation conducts their own part of the research and shares the data, each research protocol and consent process would simply follow the national liability requirements. Tables 4-1 through 4-5 list the policies for each nation impacting short- and long-term liability for subject injury. The tables identify the national laws and policies, the defence policies, and policies of subordinate defence organisations. Other relevant governmental and non-governmental policies are also listed.

There are other more complicated forms of collaboration. If TTCP researchers are collaborating at a common location and the subjects are from the host nation, the liability requirements of the host nation should take precedence over the liability requirements of the visiting researchers. If TTCP researchers are collaborating at one location but the subjects are from the participating TTCP nations, the researchers and ethics boards can look to the TTCP MOU for guidance on liability. Section XIII, Claims and Liability, states that “Except as covered elsewhere in this MOU, each Participant [e.g., the defence organisations] waives all claims against the others for injury or death of its personnel, and for damage to its property arising from the performance of official duties under this MOU.” This agreement does not limit the rights of the individual subjects to make a claim against any or all defence establishments participating in the collaboration. The section continues, “Claims from third parties [e.g., non MoD research subjects] for damages of any kind caused by one of the Participant’s personnel or agents will be processed by the most appropriate Participant, as determined by the Contributing participants. The cost incurred in satisfying such claims will be borne equally by the Contributing Participants.” Researchers should communicate with their ethics board or office early in the collaboration. If standardization of the informed consent document(s) and/or protocol are desired, early communication with the ethics office will facilitate harmonizing the liability statement.

4.1. National Policy Framework Regarding Research Liability for Australia

Members of the Australian Defence Force who volunteer as subjects for a study are considered to be “on duty” while engaged in any approved study. They therefore have the full cover associated with their employment.

Defence has a General Public Liability Policy with “Comcover” to cover Defence's legal liabilities with respect to third party bodily injury, death and/or property damage, libel, slander, defamation, and also professional indemnity, subject to policy terms and conditions. Included under Defence's General Public Liability Policy is a Medical Malpractice Policy to cover Defence's legal liabilities that may arise out of the provision, or failure to provide medical care or advice (or other medical services) in a professional capacity, subject to policy terms and conditions.



Coverage under both these policies will be provided for Defence's legal liabilities should Defence be held legally liable for an injury (bodily injury, death, sickness, disease, disability, shock, fright, mental anguish and mental injury) to a voluntary person (for example ambulance, fire, police, State Emergency Service(s) (SES), St Johns & nurses) participating in the trial in accordance with policy terms and conditions.

Under Defence's insurance program with “Comcover”, cover is not provided for workers' compensation for Australian Defence Force (ADF) or Australian Public Service (APS) employees; this is provided under “Comcare” (Military Rehabilitation & Compensation Act or the Safety, Rehabilitation and Compensation Act).

Table 4-1. National Policy Framework Regarding Research Liability for Australia

	Short-Term Liability	Long-Term Liability
Military Personnel	Defence Act 1903 Veterans' Entitlements Act 1986 Safety, Rehabilitation and Compensation Act 1988 Military Rehabilitation and Compensation Act 2004	Defence Act 1903 Veterans' Entitlements Act 1986 Safety, Rehabilitation and Compensation Act 1988 Military Rehabilitation and Compensation Act 2004
Defence Civilian Personnel	Defence Act 1903 Safety, Rehabilitation and Compensation Act 1988 OHS Act 1991 OHS (Commonwealth Employment)(National Standards) Regulations 1994 “Comcare” oversees safety, rehabilitation and compensation services for employees and employers of the Commonwealth Government. It reports to the minister for Employment and Workplace Relations and administers both the OH&S Act 1991 and the Safety Rehabilitation and Compensation Act 1988 (see above).	Defence Act 1903 Safety, Rehabilitation and Compensation Act 1988 OHS Act 1991 OHS (Commonwealth Employment)(National Standards) Regulations 1994 “Comcare” oversees safety, rehabilitation and compensation services for employees and employers of the Commonwealth Government. It reports to the minister for Employment and Workplace Relations and administers both the OH&S Act 1991 and the Safety Rehabilitation and Compensation Act 1988 (see above).

4.2. National Policy Framework Regarding Research Liability for Canada

Table 4-2 identifies the framework that may address compensation in the case of disability or death of DND military and civilian participants as a result of participation in DND sponsored, supported or conducted research projects.

As indicated in the first two rows of Table 4-2, participants may apply to two different Boards according to whether a participant is a DND civilian employee or a DND military member. DND military personnel may apply to the Veterans Review and Appeal Board. This Board is responsible to determine if the individual meets the requirements for compensation or pension based on the criteria established by legislation.

Military may also be entitled to remuneration, under Compensation and Benefits Instructions (CBI) 205.48, where exposure to abnormal stress and discomfort is anticipated in the context of



testing or research. Such remuneration is not intended to distort or influence the subject's freedom of choice.

DND civilian personnel may apply to the Workers' Compensation Board in each of the relevant provinces in the event of disability or death as a result of participation in DND sponsored, supported or conducted research project. The Board is responsible to determine if the individual meets the requirements for compensation or pension.

In all instances where the DRDC Human Research Ethics Committee reviews and approves a research protocol, the consent form includes the statement: "Should I have any questions or concern regarding this project before, during, or after participation, I understand that I am encouraged to contact the appropriate DRDC research centre cited below." This could include participants' rights and whom to contact in the case of an incident or injury.

Table 4-2. National Policy Framework Regarding Research Liability for Canada

	Short-Term Liability	Long-Term Liability
Military Personnel	<p><u>National</u>: not specified in TCPS <u>DND</u>: DAOD 5061-1: Military personnel may apply to the Veterans Review and Appeal Board in the event of disability or death as a result of participation in MOD sponsored, supported or conducted research project. The Board is responsible to determine if the individual meets the requirements for compensation or pension. Stated in DAOD Consent Form Compensation and Benefits Instructions (CBI) 205.48: Military personnel may also be entitled to remuneration, where exposure to abnormal stress and discomfort is anticipated in the context of testing or research.</p>	<p><u>National</u>: not specified in TCPS <u>DND</u>: DAOD 5061-1: Military personnel may apply to the Veterans Review and Appeal Board in the event of disability or death as a result of participation in MOD sponsored, supported or conducted research project. The Board is responsible to determine if the individual meets the requirements for compensation or pension. Stated in DAOD Consent Form</p>
DND Civilian Personnel	<p><u>National</u>: not specified in TCPS <u>DND</u>: DAOD 5061-1: DND civilian personnel may apply to the Provincial Workers' Compensation Board in the event of disability or death as a result of participation in DND sponsored, supported or conducted research project. The Board is responsible to determine if the individual meets the requirements for compensation or pension. Stated in DAOD Consent Form</p>	<p><u>National</u>: not specified in TCPS <u>DND</u>: DAOD 5061-1: DND civilian personnel may apply to the Provincial Workers' Compensation Board in the event of disability or death as a result of participation in DND sponsored, supported or conducted research project. The Board is responsible to determine if the individual meets the requirements for compensation or pension. Stated in DAOD Consent Form</p>

4.3. National Policy Framework Regarding Research Liability for New Zealand

The Injury Prevention, Rehabilitation and Compensation (IPRC) Act (2001) and Accident Compensation Corporation (ACC) Scheme provides the only source of compensation. Subjects are unable to sue for compensation in New Zealand. The only liability arising from the HSE Act is liability for the fine if prosecution eventuated.



Table 4-3 outlines the New Zealand national policies that address the care and compensation in the event of injury. Any injury occurring whilst participating in research would be covered by these policies. There are no specific Defence policies because the key feature of the liability area within New Zealand is the presence of a “no fault” approach under the IPRC which is the current legislation that the ACC Scheme operates to. This means there is no liability placed on the researcher as long as the research has been appropriately approved. The limits on the length and type of care are determined on a case by case basis.

For military personnel initial medical care would be provided by New Zealand Defence Force medical services with subsequent follow up rehabilitation and treatment being covered by ACC.

Were a Defence civilian to be injured then initial care would be provided by their own medical arrangements but the costs associated and liability for them would once again be covered by the ACC.

Were other TTCP nations military personnel or defence civilians to be injured in New Zealand as part of collaborative research, then they would be covered by ACC as they are in country as a “visitor” whilst they are in country. Note this coverage would only apply for the period those personnel were in New Zealand.

Were NZDF military personnel or Civilians to participate in research undertaken overseas under the auspices of another TTCP country’s researcher then the insurance covering their posting overseas would cover immediate costs of care until they return to New Zealand and then ACC would cover any ongoing care.

Table 4-3. National Policy Framework Regarding Research Liability for New Zealand

	Short-Term Liability	Long-Term Liability
Military Personnel	Injury Prevention, Rehabilitation and Compensation Act 2001 Health and Safety in Employment Act 1992	Injury Prevention, Rehabilitation and Compensation Act 2001
Defence Civilian Personnel	Injury Prevention, Rehabilitation and Compensation Act 2001 Health and Safety in Employment Act 1992	Injury Prevention, Rehabilitation and Compensation Act 2001

4.4. National Policy Framework Regarding Research Liability for the United Kingdom

The UK MoD operates a formal no-fault compensation scheme, which applies to participating volunteers in research activities. This scheme allows for payment of no-fault compensation to volunteers who suffer illness and/or personal injury as a direct result of participating as a healthy human volunteer in research conducted on behalf of the MoD. The no-fault compensation arrangements only apply to volunteers (military, civilian or non-MoD) who participate in a trial that has been approved by the MoD Research Ethics Committee (MODREC). No-Fault Compensation must be available to MoD/UK Armed Forces personnel in overseas trials for ethical approval to be given.



A volunteer wishing to seek no-fault compensation should contact the Directorate of Safety and Claims (DS&C), who will consider reasonable requests for imbursement of expenses incurred by volunteers in relation to pursuing their claim. This can, for example, be in relation to costs such as private medical advice, clinical tests and legal advice.

If an injury is seriously sufficient to warrant an internal MoD inquiry, any settlement may be delayed at the request of the volunteer until the outcome is known and made available to the volunteer in order to inform his or her decision about whether to accept no-fault compensation or proceed with a common law claim. An interim payment pending any inquiry outcome may be made in cases of special need. It is the Claimant's responsibility to do all he or she can to mitigate his or her loss.

In order to claim compensation under these no-fault arrangements, a volunteer must have sustained an illness and/or personal injury as a direct result of participation in a trial. A claim must be submitted within three years of when the incident, giving rise to the claim, occurred or, if symptoms develop at a later stage, within three years of such symptoms being medically documented.

The fact that a volunteer has been formally warned of possible injurious effects of the trial upon which a claim is subsequently based does not remove MoD's responsibility for payment of no-fault compensation. The level of compensation offered is determined by taking account of the level of compensation that a court would have awarded for the same injury, illness or death had it resulted from the Department's negligence.

In assessing the level of compensation, DS&C, in line with common law principles, will take into account the degree to which the Claimant may have been responsible for his/her injury or illness and a deduction may be made for contributory negligence accordingly.

In the event of DS&C and the injured party being unable to reach a mutually acceptable decision about compensation, the claim is presented for arbitration to a nominated Queen's Counsel. DS&C undertake to accept the outcome of any such arbitration. This does not affect in any way the rights of the injured party to withdraw from the negotiation and pursue his/her case as a common law claim through the Courts.

Table 4-4. National Policy Framework Regarding Research Liability for the United Kingdom

	Short-Term Liability	Long-Term Liability
Military Personnel	Annex B in the MODREC JSP 536 outlines the procedure for a no-fault compensation payment to human volunteers. This applies to military, civilian and non-ministry of defence individuals who participate in a trial or research that has been approved by MODREC	Same as short-term liability
MoD Civilian Personnel	As above	As above



4.5. National Policy Framework Regarding Research Liability for the United States

Table 4-5 identifies the national and DoD policies that address an institution's liability for providing care and compensation to subjects in case of injury as a result of their participation in the research. Each DoD Component may impose a stricter requirement for indemnification of expenses. The United States does not have a national policy requiring indemnification of subjects for costs resulting from injury. The national and Defense policies state that for research involving more than minimal risk, the informed consent process must explain to the subjects whether any compensation is available if injury occurs and whether any medical treatments are available if injury occurs and, if so, what they consist of (see 32 CFR 219.116 and DoDD 3216.02 paragraph 5.3.4, respectively). Additionally, the consent process must also include an explanation of who to contact for answers regarding the research and research subjects' rights and who to contact in the event of a research-related injury to the subject.

The Defense policy goes further than the national policy and requires that subjects be indemnified from expenses as a direct result of participation in all research that is greater than minimal risk and conducted by the DoD. Greater than minimal risk protocols conducted by the DoD must describe provisions for medical care in case of injury. The requirement for indemnification of subjects does not depend on the status of the subject (e.g., military, civil servants, or the public). Some researchers limit their subject pool to military personnel or their family members who are entitled to DoD funded health care.

When DoD researchers are collaborating with other TTCP nations, the requirements for indemnification are less clear. When DoD personnel are engaged as researchers and the DoD is not the primary sponsor of the collaboration, there is no federal or DoD requirement for indemnification (but there may be a DoD Component requirement). However the researcher is still bound by the requirements in 32 CFR 219 and must explain any compensation or provisions for medical care for research greater than minimal risk. If the primary sponsor of the collaboration is the DoD, the subjects must be indemnified from expenses in accordance with DoDD 3216.02. When the DoD personnel are research subjects in another nation, there is no federal or DoD policy to require the host nation to indemnify the subjects.

Table 4-5. National Policy Framework Regarding Research Liability for the United States

	Short Term Liability	Long Term Liability
Military Personnel	<p><u>National:</u> 32 CFR 219.116 requires only that the liability, if any, is stated in the Informed Consent Document (ICD)</p> <p><u>DoD:</u> DoDD 3216.02, para 5.3.4 states that for DoD conducted research, subjects will be indemnified from treatment expenses</p> <p><u>Intra-DoD:</u> some DoD Components restrict subjects in high risk studies to those that are eligible for military medical benefits (all military are eligible for DoD provide care)</p>	Same as short-term liability.



	Short Term Liability	Long Term Liability
DoD Civilian Personnel	<p><u>National:</u> 32 CFR 219.116 requires only that the liability, if any, is stated in the ICD</p> <p><u>DoD:</u> DoDD 3216.02, para 5.3.4 for DoD conducted research, subjects will be indemnified from treatment expenses</p> <p><u>Intra-DoD:</u> some DoD Components restrict subjects in high risk studies to those that are eligible for DoD medical benefits (i.e., those civilians eligible for routine and emergency care)</p>	Same as short-term liability.

5. NATIONAL POLICY FRAMEWORK REGARDING DATA COLLECTION, USE AND SHARING

Often collaborations within Technical Panels, Action Groups or Project Arrangements involve building a common database. One example is when researchers plan to conduct the research within their own nation, use their own subjects, and write their own research protocol. But they want to use a common research design and data collection tools to facilitate the sharing of data and to possibly construct a combined dataset. In this example, TTCP researchers would likely prepare, seek approval, and conduct the research within their own nation and according to their own nation's requirements. Additionally, the researchers would seek approval (if required) to share their data and include data from the collaborating nations. The approval of this study poses two unique regulatory challenges due to the nature of the collaboration. First, the ethics boards from each nation will each want to review and approve the data collection tool(s). Since each board will want to review the "final" version, there could be an endless cycle of edit and review. The second challenge is to develop a data sharing agreement that will accommodate the requirements of each nation. Data sharing can be very simple or very complex, depending on how the data were collected, the nature of the data, and how the data will be used.

As described in [Chapters 2](#) and [3](#), the policies governing the collection of human subject data and the definition of human subject research vary across nations. Moreover, some nations have policies that exclude from ethics review certain categories of human subject research. However, each of the five TTCP member nations have a common human research ethics framework based on the principles of justice, beneficence, and respect for the individual. When an appropriate national authority(s) has reviewed an activity and determined it to not require review and approval by an ethics board or when an ethics board has reviewed and approved a research study, collaborating nations should recognize the research contribution as ethically compliant, even if their standards differ. Different policies and standards should not hinder the ability to collaborate and share data that were ethically collected. It is reasonable for collaborating nations to request each nation "certify" that their contributions are in compliance with their nation's policies.

Research is often conducted using existing data – data from previous research or data collected for non-research purposes. Some countries have national policies requiring subsequent use of data to be approved by the subjects. Either subjects can give informed consent for future use of their data during the original study or subjects can be contacted after the initial study for permission to use their data for another study. Sometimes the requirement for informed consent



of future use of a subject's data can be waived if the data become deidentified (i.e., action is taken to make the data anonymous). A waiver may also be granted if the ethics board determines that the nature of the second study is similar to the purpose of the original data collection or if obtaining consent is impracticable and subsequent use of the data are determined to not harm a subject. The requirement for consent to use existing data for research can also depend on whether or not the original purpose of the data collection was research. If the original purpose was not research, then the individuals might not have to give their consent for secondary use, but the policies that governed the initial data collection would apply (in addition to the human research protection policies). Because there are so many variables, researchers are encouraged to contact their national point(s) of contact for ethics review to determine what requirements apply to their situation and how to structure their consent process to maximize the flexibility to reuse the data in the future.

Whenever data are shared with another nation, there should be a written agreement signed by all participants as to how the data will be used, stored, destroyed and if subsequent or secondary use is authorized. This data sharing agreement is different from a TTCP project arrangement or other collaborative agreement under TTCP 201 or the TTCP MOU. The Model Confidentiality Agreement for sharing information in Appendix 3 of the TTCP MOU (Amendment 1) is insufficient to cover the ethical requirements of nations' human research policies. The data agreement should specifically address methods for maintaining confidentiality and privacy of the data and other protections to support the nation's policies for personal information from human subjects. To facilitate the sharing of data, the researchers should contact their research ethics board or office as early as possible to discuss the creation of the data sharing agreement. This agreement will take time and can be processed while the protocol is in the early stages of review in each nation.

TTCP nations have special policies for sharing data. Often the policy and procedures depend on the source of the data and if individual subject's data can be reasonably identified. Tables 5-1 through 5-5 list each nation's policies for sharing data collected by different types of activities. Recall that each nation has slightly different standards for deciding what activities are covered under their human subject research policies (see [Chapter 3, Definition of Research](#)).

5.1. National Policy Framework Regarding Data Collection, Use and Sharing for Australia

Databanks and data banking provide some interesting considerations. The National Statement requires that when researchers are collecting data for deposit in a databank they need to specify to participants whether data will be stored in identifiable, re-identifiable (via coding key), or non-identifiable form and whether usage will be for specific, extended or unspecified future research. It also requires that any restrictions on the use of participants' data should be recorded, and accessible to all future users, as part of the data set.

If research involves the use of existing collections of data or records that contain only non-identifiable data about human beings, then an institution may choose to exempt such research from ethical review. However it should be noted that this is a positive action through a process formalized by that institution. The National Statement requires that institutions establishing non-HREC reviews should have the appropriate resources to carry out these reviews including people



who are familiar with the National Statement and can understand the ethical issues that can arise in the research under review.

Table 5-1. National Policy Framework Regarding Data Collection, Use and Sharing for Australia

Research Elements/Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Surveys	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Interviews	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Focus groups	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Psychological testing	NHMRC Act 1992 Privacy Act	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Psychological treatment	NHMRC Act 1992 Privacy Act	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Physiological testing	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Physiological treatment	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Medical testing	NHMRC Act 1992 Privacy Act Therapeutic Goods Act	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement Therapeutic Goods Act	NHMRC National Statement Therapeutic Goods Act
Medical treatment	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Being observed by researchers	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement
Collection and use of body organs, tissues and fluids	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement



Research Elements/Types of Activities	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Persons information, in individually identifiable, re-identifiable or non-identifiable form) being accessed as part of an existing published or unpublished source or database	NHMRC Act 1992	NHMRC National Statement	ADHREC National Statement	CDSI (under review) + ADHREC	NHMRC National Statement	NHMRC National Statement

5.2. National Policy Framework Regarding Data Collection, Use and Sharing for Canada

Table 5-2 illustrates policy framework entities for Canada in addressing identifiable and not identifiable research for data collection (DC) and secondary use of data (SUD) at different organisational levels. In regards to secondary use of data, the DRDC Guidelines rely on Article 3.3 of the TCPS. As stated, the issue is of concern only when data can be linked to individuals in any manner such as in published reports. For identifiable data, REB approval must be sought to assure that: (a) identifiable information is essential to the research, (b) privacy of individuals, confidentiality of data, and minimization of harm are respected, and (c) there is no objection to secondary use of the data by the individuals involved. To address (c), the DRDC Human Research Ethics Committee (HREC) is now incorporating the following statement in its voluntary consent form:

Secondary Use of Data: I consent/do not consent (delete as appropriate) to the use of my experimental data in this study in unidentified form in future related studies provided that review and approval have been given by DRDC HREC.

Volunteer's Signature _____ Date _____

Table 5-2. National Policy Framework Regarding Data Collection, Use and Sharing for Canada

Data Type	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Identifiable: Research (e.g., not medical or survey data)	Privacy Act re handling and right to access for both DC and SUD	TCPS re DC; TCPS S.3 re REB approval for SUD	DAOD 5061-0 and CANFORGEN 198/08 re DC & SUD requires REB approval; consent required	Data analysis is part of design in DC DAOD 5061-0, CANFORGEN 198/08, DRDC Guidelines, & TCPS re DC; TCPS S.3 re REB approval for SUD	TCPS re DC; TCPS S.3 re REB approval for SUD	TCPS re DC & REB-approved SUD for hospital, university, etc. HSR funded by Tri-Council grants



Data Type	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Identifiable: Medical research	Privacy Act & provincial personal health info Acts re handling and right to access for both DC and SUD	TCPS re DC; TCPS S.3 re approval by REB for SUD; consent required	DAOD 5061-0 re DC & approval by REB for SUD; consent required	As above	TCPS re DC; TCPS S.3 re REB approval for SUD	As above
Identifiable: research by survey (including naturalistic observations)	Privacy Act re handling and right to access for both DC and SUD	TCPS re DC; TCPS S.3 re approval by REB for SUD	DAOD 5061-0 and CANFORGEN 198/08 re DC & approval by REB for SUD; consent required	As above	TCPS re DC; TCPS S.3 re REB approval for SUD	As above
Not Identifiable: Research	Not applicable	SUD not subject to REB review	DAOD 5061-0 and CANFORGEN 198/08 DC & SUD not subject to REB review	DRDC Guidelines do not apply SUD not subject to REB review	Not addressed	Not addressed
Not Identifiable: Medical	Canadian law & public policy re dignity of human tissue	TCPS requires REB approval; donor consent not required	DAOD 5061-0: medical specimens not subject to REB review	DRDC Guidelines do not apply TCPS requires REB approval; donor consent not required	TCPS requires REB approval; donor consent not required	For TCPS funding need REB approval but no consent
Not Identifiable: Survey	Not applicable	Not addressed	DAOD 5061-0: DC & SUD not subject to REB review; CANFORGEN 198/08 applies	DRDC Guidelines do not apply	Not addressed	Not addressed
Criteria for Anonymous or Anonymized Data	Privacy Act as applicable	Cannot be linked to individuals	Cannot be linked to individuals	Cannot be linked to individuals	Cannot be linked to individuals	Cannot be linked to individuals for TCPS funding

Note 1: Identifiable: Research (e.g., not medical or survey data) in Row 1 implies physiological and behavioral (excluding survey) data in Canada's case.

Note 2: TCPS implies that **anonymous data** is that which cannot be identified due to absence of tags and records or passage of time; **anonymized data** is that which was originally identified but has been stripped of its identifiers.



5.3. National Policy Framework Regarding Data Collection, Use and Sharing for New Zealand

The principal legal constraint on research involving human participants is the Privacy Act 1993 and the Official Information Act 1982 also applies. The Privacy Act protects the privacy of all natural persons (even foreign persons) against the information collection and use activities of any agency in New Zealand. An agency which holds personal information must not disclose that information to another person, body or agency except with the authorization of the individual to whom the information pertains. This is subject to ten exceptions outlined in the act. Of these Principle 10 covers limits on use of personal information and it does allow information to be used for a new purpose but only if the individual is not identified. Annex B of DFO 21/2002 contains the ethical guidelines for Personnel Research and outlines the requirements for Informed Consent.

In addition Defence Force Order 15/2003 outlines how information gathered by NZDF Psychologists can be used and DFO 10/2003 outlines how the issues raised by the Privacy Act are to be dealt with within the NZDF.

The New Zealand Psychological Society Code of Ethics also outlines the provisions that registered psychologists must abide by when conducting research and covers the ethical collection of data.

Where official information has been collected this information may be available for request under the Official Information Act and this could apply to survey information.

With respect to health information additional safeguards apply, e.g., Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994.

Table 5-3. National Policy Framework Regarding Data Collection, Use and Sharing for New Zealand

Data Type	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Identifiable: Research (e.g., not medical or survey data)	Privacy Act 1993	Privacy Act 1993	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003



Data Type	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Identifiable: Medical	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994 DFO 21/2002 DFO 15/2003 DFO 10/2003
Identifiable: Survey	Privacy Act 1993	Privacy Act 1993	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003
Not Identifiable: Research	Privacy Act 1993	Privacy Act 1993	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003
Not Identifiable: Medical	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 Health (Retention of Health Information) Regulations 1996 and Health Information Privacy Code 1994 DFO 21/2002 DFO 15/2003 DFO 10/2003
Not Identifiable: Survey	Privacy Act 1993	Privacy Act 1993	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003
Criteria for Anonymous Data	Privacy Act 1993	Privacy Act 1993	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003	Privacy Act 1993 DFO 21/2002 DFO 15/2003 DFO 10/2003



5.4. National Policy Framework Regarding Data Collection, Use and Sharing for the United Kingdom

The MoD has a number of Defence Contracts (DEFCONs), agreed centrally by MoD with industry and academia, which are in common usage in MoD contracting. DEFCON 705 requires that Technical deliverables are marked in an appropriate manner to make clear ownership of Intellectual Property rights. Despite this, the MoD has the right to use in confidence all technical information provided in pursuance of the contract for:

- a. any purpose within a UK Government Department.
- b. authorization of use for the purpose of implementing a defence agreement, provided that where such disclosure is made to a foreign government or international organisation in pursuance of arrangements for shared defence or security or intelligence, no onward disclosure outside the receiving party shall be permitted.

However, all MoD data collected as part of a research programme must comply with the Data Protection Act 1998, the Freedom of Information Act 2000 and the Access to Health Record Act 1990.

Those involved in research have an ethical and legal obligation to respect the confidences of individual research participants. This obligation extends to all personal information, medical or otherwise. The participant may, of course, consent to information being disclosed.

If researchers plan to share information with another party this must be declared on a Participant Information Sheet and agreed by the participant when they sign a consent form. In circumstances where the researchers anticipate that they wish to re-contact participants regarding the use of data for purposes other than those specified in the Participant Information Sheet or to invite them to participate in further studies, consent to be re-contacted must be given by the participant on the consent form.

Ordinarily the application should refer to the need to obtain express permission if confidential information is to be used in a manner which will identify the research participant. Similarly, the researchers should consider, and disclose in the application, any action that would need to be taken if circumstances were discovered which would give rise for concern (e.g. indication of a health issue, suggestion of professional misconduct).

If it is possible that information may come to light during the study which should be passed on to a third party (e.g. evidence of professional misconduct, information that should be passed on to a participant's General Practitioner (GP) the participant should be advised of this possibility in the consent form and/or Participant Information sheet.

Details concerning confidentiality must be accurate and not capable of misleading potential participants.

The Participant Information Sheet or consent form should clearly state if participant details are to be passed to any other organisation.



There are exceptions to the obligation of confidentiality which justify disclosure. All such disclosures must comply with the Data Protection Act and include:

- a. **Public interest.** There may be circumstances where the right to confidentiality must be weighed against the public interest where there is a real or serious risk that another, or the public at large, may be put in danger by the participant.
- b. **Research records.** Principal Investigators must ensure that proper records are kept throughout the active period of research. Records of personal details (name, address, telephone numbers) must be kept in a secure place along with any information of a medical nature (e.g. health screening questionnaire, details of drug usage). These records are kept separately from research records which ideally should be represented by a code number rather than a name. In tables of data, participants must only be identified by number not by their name or initials.
- c. **Storage of Documents.** A copy of the Participant Information Sheet is given to the participant to keep. The signed copy of the consent form is retained, along with all other paperwork, relevant to the experiment, in a secure location, accessible for inspection if required, for at least 100 years after the work has completed.
- d. **Data Protection.** All research participants have a right to inspect the record of their participation.
- e. **Audit.** Records may need to be inspected for audit purposes either during the experiment or during the period of storage.

Table 5-4. National Policy Framework Regarding Data Collection, Use and Sharing for the United Kingdom

Data Type	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Identifiable Research: Research	Data Protection Act 1998 Freedom of Information Act 2000	All research organisations must comply with legal acts.	As set out by MoDs contracting organisation DTIC that sets up	See Defence column	All must comply with the legal acts mentioned in the “legal framework” column	See Defence column
Identifiable: Medical	Data Protection Act 1998 Freedom of Information Act 2000 Access to Health Records Act 1990	All research organisations must comply with legal acts.	defence contracts. Under DEFCON 705 all research funded by the MoD is allowed to be	See Defence column	All must comply with the legal acts mentioned in the “legal framework” column	See Defence column
Identifiable: Survey	Data Protection Act 1998 Freedom of Information Act 2000	All research organisations must comply with legal acts.	freely used within the MoD irrespective	See Defence column	All must comply with the legal acts in the “legal framework” column	See Defence column



Data Type	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Non-identifiable: Research	Data Protection Act 1998 Freedom of Information Act 2000	All research organisations must comply with legal acts.	of who owns the intellectual property rights. All classified	See Defence column	All must comply with the legal acts mentioned in the “legal framework” column	See Defence column
Non-identifiable: Medical	Data Protection Act 1998 Freedom of Information Act 2000 Access to Health Records Act 1990	All research organisations must comply with legal acts.	research is assessed on a “need to know” basis and is shared accordingly. All unclassified research is encouraged to be published in a peer reviewed journal, this would allow easy sharing.	See Defence column	All must comply with the legal acts mentioned in the “legal framework” column	See Defence column
Non-identifiable: Survey	Data Protection Act 1998 Freedom of Information Act 2000	All research organisations must comply with legal acts.		See Defence column	All must comply with the legal acts mentioned in the “legal framework” column	See Defence column
Criteria for anonymous data	Anonymous data must have all individual identifiers removed (for example name, date of birth, address). Also, data published must have identifiers removed that could lead to the identifying of a participant using other public domain sources (for example, data stating the sex of a certain injury type – if there were only a couple in this category, sources such as newspapers might further identify an individual)					

5.5. National Policy Framework Regarding Data Collection, Use and Sharing for the United States

The US has three key national policies governing the collection and use of personal information. The first policy is the Federal Policy for the Protection of Human Subjects, 32 CFR 219, and it covers research data involving human subjects. The policy exempts certain types of existing data or categories of research from review and approval from the Institutional Review Board (IRB) and from prior consent from the participants (see 32 CFR 219.101(b)). This exemption is commonly used for three types of research. Section 32 CFR 219.101(b)(1) exempts research where the only interaction or intervention with a subject is the use of normal educational practices in commonly accepted educational settings or research on the effectiveness of training. For the military, common educational settings may include simulation centers and outdoor training locations. The second common exemption is described in section 32 CFR 219.101(b)(2). Research can be exempt if there is no intervention and the only interaction is an educational test, survey, or interview where either the data are recorded anonymously or any disclosure of the data could not put the subject at risk of harm. The third common category of exemption is research using only existing data or specimens if the data are recorded



anonymously (the source data may be identifiable) or are available to the public 32 CFR 219.101(b)(4). Research that is exempt from IRB review and approval should still respect the rights and welfare of the subjects. The process of informed and voluntary consent is often followed in work that is not covered by or exempt from 32 CFR 219.

If a DoD researcher is engaged in human subject research that involves existing data or specimens and the research does not meet one of the exemption criteria, the research will have to be conducted under a DoD Assurance and be reviewed and approved by an IRB (possibly by expedited review) and the subjects will have to provide their informed consent to use their data (unless the IRB waives informed consent in accordance with 32 CFR 219). If the data or specimens cannot be identified and there is not a code to link the data to the subject's identity, the collaborative research is exempt. This means an assurance is not needed and the IRB does not have to review and approve the research.

If a DoD member intends to share identifiable or coded research data or specimens with TTCP members, a data-use agreement should be established. Such a data transfer may constitute a "supported" human subject research activity in the context of 32 CFR 219. ("Supported" means providing not only DoD funds but also DoD personnel, DoD data, or DoD equipment. If the research is supported by DoD, the recipient TTCP institution is obligated to obtain a US federally approved assurance, obtain IRB approval, and conduct the human subject research in accordance with 23 CFR 219 and DoDD 3216.02.) If the DoD is providing coded or identifiable data, the data-use agreement should state that the recipient will follow their nation's policies and procedures for the review and approval of the research in addition to DoD policies. If the shared data or specimens cannot be identified and there is not a code to link the data to the subject's identity, the research is exempt from the assurance and IRB requirements identified in 32 CFR 219. Still, a data-use agreement should still be used.

The second national policy, Health Insurance Portability and Accountability Act (HIPAA), covers medical information collected by covered entities such as health care institutions and providers. The Privacy Rule of this Act covers the security and privacy of health data and regulates the use and disclosure of private health information. The Act may require a research protocol be approved by a HIPAA Privacy Board and the use of the data be approved by the subject patient. The HIPAA Privacy Board may or may not be the same approving authority as the IRB (under 32 CFR 219). The Act also defines criteria for data to be anonymous. DoD has implemented the requirements in HIPAA in DoD 8580.02-R, "DoD Health Information Security Regulation."

The third national policy, the Privacy Act, states that the federal agencies "shall not disclose any record which is contained in a system of records by any means of communication to any person, or to another agency, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains...." DoD Regulation 5400.11-R, Department of Defense Privacy Program," implements the Privacy Act for all DoD information and systems of records. DoD Instruction 1100.13 implements the Privacy Act with respect to surveys.



Table 5-5. National Policy Framework Regarding Data Collection, Use and Sharing for the United States

Data Type	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Identifiable: Research (e.g., not medical or survey data)	32 Code of Federal Regulations, Part 219 (32 CFR 219)	32 CFR 219	DoD Directive 3216.02 (DoDD 32 61.02)	Each of the 11 DoD Components conducting or sponsoring human subject research have implementing policies and procedures (e.g., Army Regulation 70-25 ; SECNAVINST 3900.39D ; Air Force Instruction 40-402)	Each federal agency (e.g., Dept of Health and Human Services) has the same language as 32 CFR 219 in their title of the CFR (e.g., DHHS is at 45 CFR 46)	Follows the Federal Policy (e.g., 32 CFR 219 or 45 CFR 46) when research is sponsored by a federal agency
Identifiable: Medical	32 CFR 219 Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191 and 45 Code of Federal Regulations Parts 160,162, and 164 (45 CFR 160, 162, and 164)	32 CFR 219 The Health Insurance Portability and Accountability Act (HIPAA)	DoDD 3216.02 DoD 8580.02-R DoD Regulation 5400.11-R	Each of the 11 DoD Components conducting or sponsoring human subject research have implementing policies and procedures (e.g., Army Regulation 70-25 ; SECNAVINST 3900.39D ; Air Force Instruction 40-402)	Each federal agency (e.g., Dept of Health and Human Services) has the same language as 32 CFR 219 in their title of the CFR (e.g., DHHS is at 45 CFR 46)	Follows the Federal Policy (e.g., 32 CFR 219 or 45 CFR 46) when research is sponsored by a federal agency HIPAA
Identifiable: Survey	32 CFR 219 Privacy Act of 1974 , Section 522a of Title 5, United States Code (5 USC 522a) and Public Law 93-579	32 CFR 219 Privacy Act of 1974	DoDD 3216.02 DoD Instruction 1100.13	Each of the 11 DoD Components conducting or sponsoring human subject research have implementing policies and procedures (e.g., Army Regulation 70-25 ; SECNAVINST 3900.39D ; Air Force Instruction 40-402)	Each federal agency (e.g., Dept of Health and Human Services) has the same language as 32 CFR 219 in their title of the CFR (e.g., DHHS is at 45 CFR 46)	Privacy Act of 1974
Not Identifiable: Research	32 CFR 219	32 CFR 219	DoDD 3216.02			None
Not Identifiable: Medical	32 CFR 219 HIPAA	32 CFR 219 HIPAA	DoDD 3216.02 DoD 8580.02-R			HIPAA



Data Type	Legal Framework	National Policy	Defence	Defence Research Organisation	Other Government Research Organisations	Non-Government Organisations
Not Identifiable: Survey	32 CFR 219 Privacy Act of 1974	32 CFR 219 Privacy Act of 1974	DoDD 3216.02 DoD Instruction 1100.13			Privacy Act of 1974
Criteria for Anonymous Data	32 CFR 219 HIPAA	32 CFR 219 HIPAA	DoDD 3216.02 DoD 8580.02-R			HIPAA

6. CONSIDERATIONS FOR INFORMED CONSENT WHEN COLLABORATING WITH OTHER TTCP NATIONS

The ethical principle of free and informed consent is a core tenet of each TTCP nation's policy framework. Informed consent is not just a document but a process that starts with recruiting and ends when the study is over. Each nation requires their ethics board to review and approve the entire consent process – such as advertisements for subjects, recruiting scripts and all information presented to the subjects.

Informed consent usually occurs in advance of the study, but there are acceptable reasons for delaying or altering consent such as when conducting deception research. Some national policies allow waiving documentation of informed consent under very specific conditions. Researchers can request consent directly from the subjects or from their legally authorized representative when the subject is unable to provide a response. Deception research, waiving informed consent, and obtaining informed consent from legally authorized representatives will not be addressed in this section.

Over time the legal community has become more involved with inserting clauses in the consent document to protect the institution. This has resulted in the document becoming longer, more complex, and less able to meet its primary purpose – to inform the subject. Researchers are used to writing long, technical sentences for their peers. Therefore, researchers have to be mindful when preparing material for subjects to ensure the materials are presented at an education level understood by all the potential subjects. TTCP nations are divided by a common language. Word choice is critical when collaborating with TTCP nations.

National policies vary in the latitude offered in the choice of modes of communication and documenting informed consent. Subjects can become informed and indicate their consent using only verbal communication, using only written communication, or more commonly using a mixture of the two. Recording informed consent can happen in many ways, such as having the subject sign a document stating they have understood the information presented and volunteer to participate, having a researcher or witness document informed consent was given (if there is a risk to having the subject's name recorded), or can be implied by having the subject participate (completion of a survey). Each ethics board approves the mode of communication and documentation of informed consent.



The researcher's preparation and the ethics board review of the consent process typically focuses on the Participant Information Sheet and/or the Informed Consent Document. The materials used in the recruiting process rarely receive the same scrutiny as the materials specifically used to obtain the informed consent of the subjects. Special concern should be given regarding coercion, undue influence, confidentiality, and privacy when recruiting military and civil servants as subjects. Defence personnel serve in a strict hierarchical culture and are trained to respect rank. They are susceptible to directives or requests from senior officials. The military implicitly agree to subordinate their autonomy for the sake of accomplishing the mission. They agree to risk personal injury or loss of life, if need be, in compliance with lawful orders of their superiors. Defence personnel have a unique risk of disqualifying consequences from disclosure of sensitive information, information that may not be sensitive or have the same impact if disclosed for private citizens. The requirement for the "Duty to Report" certain behaviors and medical conditions are different for military and civil servants than for private citizens. These are just a few of the many unique concerns that must be considered when recruiting military or civil servants.

A short description of and references for each nation's informed consent requirements are provided in sections 6.1–6.5 below. Table 6-1 lists the key elements required by all TTCP nations in a Participant Information Sheet/Consent Document and identifies the minimum common wording or requirements to address that are acceptable to all or most nations. Again, national policies are in close agreement as to the elements in the informed consent documentation. The national policies rarely specify exact language. So the ethics board should work with TTCP researchers to agree to common language that is acceptable to all and meets the ethical national requirements. These statements or requirements are not in the order they should appear in the consent document; they are grouped by topic. This table does not reflect all of the necessary statements needed to result in fully informing the subject about the research. Nations differ on the perspective from which the consent document should be written. Taking the perspective of the subject, the document would be written in the first person and use the phrase "I understand." Taking the perspective of the researcher, the document would be written in the second person and use the phrase "you understand." In either case, the statements in the table should be edited for organisation and flow so that there is not a page full of sentences starting with "I/you understand..." For example, all of the requirements could be described and the document concluded with a short section that begins with, "I understand the information presented to me..."

6.1. National Policy Framework Regarding Informed Consent for Australia

Guideline 4.8.1 of the National Statement specifies that "research conducted overseas by researchers from Australian institutions must comply with this National Statement."

The National Statement dedicates a chapter to the General Requirements for Consent (Chapter 2.2), and another chapter to Qualifying or Waiving Conditions for Consent (Chapter 2.3). Key requirements for consent are that this consent be free and based on being well-informed about the implications of participation. The latter consideration leads to the associated requirements for participants to have an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research (National Statement, paragraph 2.2.2). Of particular note is that



only HRECs can review and approve research that either involves active concealment or planned deception, or that aims to expose illegal activity.

Health Manual (Volume 23, paragraph 4.12) details the format for the Information Sheet and Informed Consent Form meeting minimal requirements standard.

6.2. National Policy Framework Regarding Informed Consent for Canada

DAOD 5061-0 (policy), DAOD 5061-1 (procedures) and CANFORGEN 198/08 mandate that informed consent must be obtained from research participants in any human research project, and done so in accordance with the Tri-Council Policy Statement. Informed consent is defined as the voluntary agreement to become a participant in a research project, with the full understanding of the project's rationale, procedures, risks, benefits, expected outcomes, measures to ensure confidentiality, expected follow-up studies, data retention, anticipated time commitment and the intended disclosure. Moreover, consent must be sought for the secondary uses of the data concerning the research participant. A human research ethics committee must review the project protocol to ensure that these conditions are addressed.

The Tri-Council Policy Statement recognizes that the preferred method of obtaining consent is by the written word. However, there are instances where written consent is not possible, e.g., where it is not culturally acceptable, or feasible, e.g., when data are to be collected from a vast number of participants through interviews or questionnaires, postal mail, e-mail or over the phone. In the latter case, DRDC HREC employs a covering letter for unsigned consent that stipulates to the participant the voluntary nature of the project, anonymity of the person, confidentiality of data and other essential information.

Unsigned consent may be used only when:

- the research involves no more than minimal risk to the participants;
- the use of unsigned consent is unlikely to adversely affect the rights and welfare of the participant;
- the research could not practicably be carried out if signed consent was mandated;
- whenever possible and appropriate, the participant will be provided with additional pertinent information after participation; and
- the project does not involve a therapeutic intervention.

A related issue concerns the withholding of information to participants where full information may influence the outcome of the research project, e.g., the complete details of a survey may influence the response given. In those cases, the DRDC HREC requires that the protocol should be written in two parts, one having human-participant information only, the other having all of the information required for review. This withholding of information should only be used in those rare situations where:

- there is minimal risk and no other research method will provide the answers, and
- the lack of full disclosure of the research protocol is unlikely to deter the subject from participation in the research project.



When such withholding of information has been approved by the HREC, then the investigators must debrief the participants thoroughly when participation has been completed. Moreover, participants must be given the option of refusing to allow use of the data generated through their participation in the research.

6.3. National Policy Framework Regarding Informed Consent for New Zealand

The first and second schedules of Annex B to DFO 21/2002 outline firstly the scope of any research being undertaken and then the ethical guidelines for that research. Schedule Two in particular deals in some depth with the elements of informed consent that appear in Table 6-1 below. For any research under NZ control and involving other nations or nationals the research cannot proceed unless approved by both the Director of Psychology and then Assistant Chief of Personnel for the Chief of Defence Force.

The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 (SR 1996/78) (as at 03 September 2007) requires written Informed Consent to a health procedure involving research. Likewise removal of a body part or bodily substance requires informed consent and prior approval by the appropriate ethics committee.

6.4. National Policy Framework Regarding Informed Consent for the United Kingdom

Through its formal TTCP arrangements with other nations, MoD conducts some collaborative research programmes involving human participants. These collaborative programmes must undergo ethical scrutiny. Where UK MoD/Armed Forces personnel are required to participate in an overseas trial, the host nation's research protocol must be sent, along with the written review of its own ethics committee, to the MODREC for its consideration. No-Fault Compensation must be available to MoD/UK Armed Forces personnel in overseas trials for ethical approval to be given.

Written consent is required from all UK participants for all studies except those that are exclusively based on questionnaires and are not collecting sensitive data, in which case submitting a completed questionnaire implies consent. This is stated on a Participant Information Sheet.

To ensure compliance with the Data Protection Act 1988, participants must be informed of what information will be held about them and who will have access to it (this relates to personal, identifiable information). Explicit consent must be obtained for questionnaire studies in which sensitive data will be collected.

Research participants must have the right to choose whether or not they will participate in the research, and obtaining informed consent is central to the ethical conduct of all research involving human participants. Fully informed consent in this context means consent freely given with proper understanding of the nature and consequences of what is proposed. The following process is recommended to ensure that this is in place:



- a. Each participant be given an oral explanation.
- b. Each participant be given a Participant Information Sheet explaining in simple, non-technical terms, the procedures, any potential risks and perceived benefits.
- c. The participant should be given reasonable time to consider this information and to consult others as necessary.
- d. Except in the case of questionnaire based studies, the participant should be asked to sign a consent form (which should be witnessed).

Where the relationship between recruiter and potential participant might be influential, this must be acknowledged and an explanation provided on how predictable problems will be managed.

MODREC acknowledges that each experiment has different requirements and that researchers need to communicate with a wide variety of potential participants, so there needs to be some flexibility in the contents of the consent form. However, they ask that the following clauses are, at least, considered:

- a. Please inform the researcher if you are currently involved or have been involved in any other research studies in the last 12 months.
- b. Please note you should not participate in this research if you become or are likely to become pregnant.
- c. I agree to be contacted in the future by the researchers who would like to invite me to participate in follow up studies, or in future studies of a similar nature.
- d. I agree that my GP may be contacted if any unexpected results are found in relation to my health.
- e. The information you have submitted will be published as a report. Please note that confidentiality and anonymity will be maintained and it will not be possible to identify you from any publications.

6.5. National Policy Framework Regarding Informed Consent for the United States

The national and DoD policies that address the informed consent process are 32 Code of Federal Regulations Part 219 (32 CFR 219), sections 116 and 117; DoD Directive 3216.02 paragraph 4.2; and 10 United States Code 980 (10 USC 980). 32 CFR 219, section 116 identifies eight basic element of informed consent. The section also identifies six additional elements to include depending on the nature of the research. The IRB may waive some or all of the elements of informed consent under certain conditions specified in the section. The process for documenting informed consent is described in section 117. Conditions for using oral, written and signed consent forms are described in the section.

DoDD 3216.02, paragraph 4.2 references the requirements in 32 CFR 219 and 10 USC 980, and DoDD 3216.02 paragraph 4.4.4 describes additional protections for military members during the recruitment phase. DoD is limited by 10 USC 980 in the ability to waive informed consent as allowed by 32 CFR 219.116. For DoD sponsored research involving a medical product, informed consent must be obtained in advance or the Head of the DoD Component may waive the requirement for informed consent if the subject could directly benefit from participation.



Each DoD Component may impose additional requirements for informed consent. When collaborating, the researchers are strongly encouraged to contact their DoD Component headquarters oversight office (e.g., their Office of the Surgeon General or Director of Research). This office can often assist in facilitating research approval if they are involved during the development of the recruiting and informed consent material.

6.6. Common Key Elements Regarding Informed Consent

Table 6-1 outlines the common key elements needed in to be included in informed consent documents. National policies typically direct that informed consent documents address specific topics but do not provide exact language. Often, research organizations have created a template or informed consent documents that include standard clauses. Collaborators should request a template from each collaborating organization. The customary clauses can usually be modified to accommodate the needs of multiple nations. The table below provides an example of the minimum acceptable wording for the key elements to be included in the informed consent documents.

Table 6-1. Elements to Include in a Common Informed Consent Form when Collaborating with Other TTCP Nations

Elements of the Informed Consent Form	Required by TTCP Nations (Encouraged but not required by National Policy)	Minimum Acceptable Common TTCP Wording or Practice	Also “Nice to Have” TTCP Wording or Practice
<u>Study Identifiers</u>			
Full title of study	All	[Include full title of study. If the title is complicated and technical, a simple lay wording should also be provided.]	
Identify Government Organisation as sponsor	AS, CA, UK, US	[State who is sponsoring and conducting the research, including collaborators.]	Statement that the study is an international TTCP collaboration and identifying the nations.
Study contact information for the Investigator and Research Institution	All	[State the following information: 1) the name and contact information of the responsible investigator; 2) the name(s) and contact information of institutional personnel to respond to subject’s questions regarding the study, their rights, and claims; and 3) and the contact information of the approving ethics office.]	
<u>Informed and Voluntary Consent</u>			
Informed participation	AS, CA, UK, US	I have read and understood the information provided. I understand what is expected of me. All my questions have been answered fully to my satisfaction.	
Voluntary participation	All	I consent to take part in this research study on the understanding that my participation is entirely voluntary and I am under no obligation to take part.	



Elements of the Informed Consent Form	Required by TTCP Nations (Encouraged but not required by National Policy)	Minimum Acceptable Common TTCP Wording or Practice	Also “Nice to Have” TTCP Wording or Practice
Refusal to participate	All	If I choose not to take part it will not affect my career or health care.	
Withdrawal – right to withdraw at any time and consequences of withdrawal	All	I may withdraw at any time and my action will not affect my career or my health care. I do not have to give a reason to withdraw.	If it applies, explain the consequences of a subject’s decision to withdraw from the study <u>and</u> any follow-up the subject may be asked to complete, for safety reasons.
<u>Purpose of the Study</u>			
Description of the purpose of research	All	I understand that the purpose of this research study is to [simply describe what the study is designed to discover or prove].	
<u>Study Procedures</u>			
Describe the nature and procedures of research study; Describe the participant’s role in the research study	All	[Simply describe the procedures.] I understand the procedures to be followed and what is expected of me. I also understand how much of my time will be required and any restrictions I might have during the study if I participate.	Distinguish and explain what procedures, if any, are experimental versus standard clinical treatment.
Screening tests (if applicable)	All	[Simply describe the test procedures, the time required, the risks and discomfort to the subject, and the acceptance/rejection criteria]. [Simply state what results will be shared with the subject and what results must be shared with others and the potential impact.] I understand that I will participate in screening process to make sure I meet the eligibility requirements of the research study.	
<u>Potential Risks & Discomfort</u>			
Explain potential risks and discomfort of a subject	All	[For each procedure, simply describe reasonable foreseeable risks and discomfort.] I have been informed of the risks involved in the protocol and any foreseeable discomfort.	
<u>Potential Benefits to Subject</u>			
Explain the potential benefits to the subject	CA (in requirement but not Info sheet or Consent), UK (in protocol but not Info sheet or Consent), US	[Simply describe any anticipated benefits to be experienced by the subject.]	



Elements of the Informed Consent Form	Required by TTCP Nations (Encouraged but not required by National Policy)	Minimum Acceptable Common TTCP Wording or Practice	Also “Nice to Have” TTCP Wording or Practice
Compensation/ Indemnification	AS, CA, UK, US	[Use one of the following two models.] I also understand that if I am hurt or sick because of this study, I can [clearly describe the method to seek care and/or how to file a claim for compensation]. [If no compensation or medical care is available, this fact is to be stated without waiving the subject’s rights to file a claim.]	
Remuneration/ payment	AS, CA, UK,, US	[Use one of the following two sentences or a blend of both.] I understand that I will be paid [insert amount and payment schedule if early withdrawal] for volunteering for this study. or I understand that I will be reimbursed [insert for what and how much] for volunteering for this study.	
“On duty” statement for uniformed personnel and members of the Public Service	All	I understand that I will be considered to be “on duty” whilst participating in this study. I will not be compensated.	
Costs to the subjects	US	[Identify any potential costs to the subjects that will not be reimbursed.]	
<u>Privacy and Confidentiality</u>			
How to handle findings – in the data and in the screening	US	[Simply state what results must be shared with others and the potential impact of the disclosure.]	
Storage and access to subject data Subject rights to access or correct personal information	CA, NZ, UK, (US)	I understand that my personal or identifiable data will be maintained, handled, and archived in the following manner [simply describe, e.g., stored on a removable disk under lock and key under PI control or stored under password protection on institutional server]. [State if the data will be directly identifiable, coded and stored separately, deidentified, or anonymous.] [Cite any national privacy policies or language or situations where others may have access (e.g., an investigation).]	



Elements of the Informed Consent Form	Required by TTCP Nations (Encouraged but not required by National Policy)	Minimum Acceptable Common TTCP Wording or Practice	Also “Nice to Have” TTCP Wording or Practice
Prospective secondary or post-study use of data	AS, CA, NZ, (US)	Choose an appropriate statement(s): I understand my individual data may be used in future related studies, as described [simply describe]. I understand that my individual data will be used for the purpose of this study and no other reason, without my express permission. I do/do not consent to my data being used in future related studies in a deidentified form. I do/do not consent to my data being used in future related studies in an identified form.	
Publishing results	AS, CA, NZ, (US)	I understand that my data will be reported with other subjects’ data so that my data will not be identifiable. My name will not be used.	
Consent for use of visual images	AS, NZ, (US)	Choose an appropriate statement(s): I GIVE permission for the researchers to use video clips or still shots which may identify me. I GIVE permission for the researchers to use video clips, or still shots only where my face is de-pixelated (thus de-identifying me). I DO NOT GIVE permission for the researcher to use video clips or still shots that may identify me whether de-pixelated or not.	
<u>Other Elements</u>			
Process for complaints or concerns	AS, CA, NZ, UK, (US)	Should you have any complaints or concerns about the manner in which this research is conducted, please do not hesitate to contact <i>[insert Responsible Investigator and contact information]</i> , or you may prefer to contact <i>[insert person at an independent office, e.g., Ethics Office, and contact information]</i> .	
Share outcome of study with subjects (on request)	AS, NZ, UK, (US)	I understand that, upon request, I will be informed of the outcome of this study.	
Recent participation in other trials	AS, CA, NZ	Are you in any other trials at present [or have you been in any other trials recently]?	



Elements of the Informed Consent Form	Required by TTCP Nations (Encouraged but not required by National Policy)	Minimum Acceptable Common TTCP Wording or Practice	Also “Nice to Have” TTCP Wording or Practice
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	US	[Simply describe any alternative procedures that may be advantageous to the subject. Or state that there are no efficacious alternatives, other than to not participate in the study.]	
Commercialisation purposes	CA	I have been informed that the research findings resulting from my participation in this research may be used for commercialisation purposes.	

7. FREQUENTLY ASKED QUESTIONS (FAQ) IN HUMAN RESEARCH ETHICS

7.1. I am going to collaborate with another TTCP nation on research involving human subjects. How do I ensure our protocol will be compliant with each nation’s policies?

If multiple versions of the protocol and informed consent document(s) are possible, each researcher would write their version of the protocol and consent document(s) in the format required to meet their nation’s requirements. If harmonization of the documents is needed, the information contained in AG25 Final Report (DOC-HUM-2-2008) should be useful in harmonizing a core set of documents. Additionally, other FAQ provide points of contact in each nation that can assist in harmonizing the research documents and ethics reviews.

7.2. Does TTCP 201 and the TTCP MOU address collaborations involving human research?

Neither TTCP 201 (formerly known as POPNAMRAD) nor the TTCP MOU specifically address the protection of human subjects in research. TTCP has been very successful at providing a framework to facilitate collaboration in defence science and technology. The MOU allows researchers to share information and promotes joint research. There are template project agreements and data exchange agreements. There is no template or universally acceptable research protocol or consent document.

The TTCP HUM Group document entitled “A Comparison of National Policies on Research Involving Human Subjects to Facilitate Review and Approval of Collaborative Research” (DOC-HUM-2-2008) provides an introduction to and summary of relevant National policies for the protection of human subjects.



7.3. What is the purpose of the tables on the TTCP Portal?

These tables offer a quick guide to Principal Investigators in addressing questions regarding the specific national policy framework or environment in each TTCP nation for conducting human research.

- Tables 2-1 through 2-5 list the references (laws, policies, regulations, etc.) that provide the policy framework or environment for ethical human subject research for each nation.
- Tables 3-1 through 3-5 list the references (laws, policies, regulations, etc.) that provide the policy framework or environment for the definition of research involving human subjects for each nation.
- Table 3-6 provides a quick comparison of each nation's scope of the definition of research.
- Tables 4-1 through 4-5 list the references that provide the policy framework or environment for research liability for each nation.
- Tables 5-1 through 5-5 list the references (laws, policies, regulations, etc.) that provide the policy framework or environment covering data collection, use and sharing for each nation.
- Table 6-1 lists the elements to include in a common informed consent form when collaborating with other TTCP nations.

7.4. How can I find out if my project needs to be reviewed by an ethics board (e.g., the project is research involving human subjects)?

Contact your ethics board or your nation's POC in FAQ 7.13–7.17 for assistance.

7.5. My Technical Panel is preparing to collaborate on a human research study. Is there a TTCP office that can help us obtain approval from a single ethics board for streamlining multinational approval?

There is no standing TTCP office to coordinate such collaborations. Your nation's contact on AG25 can assist you (see FAQ 7.13–7.17). Each National member of AG25 and the AG25 as a whole are willing to work with you to assist in gaining approval for the collaboration.

7.6. Where can I find a list of National or Defence policies covering human research ethics and requirements?

Tables 2-1 through 2-5 address six levels in the policy framework for each TTCP nation:

- Column 1, "Legal Framework," lists the national laws and acts relevant to human subject research. These legislative elements primarily concern privacy, human rights, health/medicine, safety, and compensation. The documents in this column provide the legal basis for national and defence policies.
- Column 2, "National Policy," identifies councils, policies, statements, reports, guidelines, etc., that may not have the force of law but implement the legal documents in Column 1.
- Column 3, "Defence," identifies legally enforceable, defence directives and instructions that investigators must comply with when conducting human research.



- Column 4, “Defence Research Organisation,” refers to the organisation(s) within the DoD/DND/MoD that are involved with human research. This column identifies the specific DoD/DND/MoD institution guidelines for conducting human research that investigators must use to comply with their DoD/DND/MoD references in Column 3.
- Column 5, “Other Government Research Organisations,” cites the references used by non-defence government organisations regarding human research. These citations may or may not be included in Column 3, Defence. References in this column are important when the TTCP collaboration includes government organizations other than Defence.
- Column 6, “Non-Government Organisations,” lists the policies followed by institutions such as universities, hospitals, companies, etc. References in this column are important when the TTCP collaboration includes non-government organisations.

Additionally, Chapter 9 of the AG25 Final Report (DOC-HUM-2-2008) provides a list of references by nation.

7.7. Is there a common requirement or agreement for indemnifying subjects against expenses resulting from injury or compensation for injury?

For each of the five TTCP nations separately, Tables 4-1 through 4-5 identify the Compensation and Safety Acts and/or Regulations for conducting adjudication proceedings for short- and long-term liability in the case of disability and death for military and MoD/DoD/DND civilian personnel acting as human volunteers in experiments approved by the respective defence organisations.

7.8. What kinds of research or activities are covered by the ethics policies of each nation?

Table 3-6 provides a short list of common TTCP collaborative activities that may or may not be considered covered by each TTCP nation’s policies.

Additionally, Tables 3-1 through 3-5 lists for each TTCP nation six levels in policy framework (Columns 2–7) for identifying and conducting different types of covered research (Column 1).

- Column 1, “Research Elements/Types of Activities,” speaks to the type of federally funded or sponsored defence research the human participant undertakes in the respective TTCP nations, including personal, psychological/behavioural and medical research. In some tables, exempted research is also addressed.
- Column 2, “Legal Framework,” lists the national laws and acts relevant to each type of human subject research. These legislative elements primarily concern privacy, human rights, health/medicine, safety, and compensation. (see FAQ 7.6)
- Column 3, “National Policy,” identifies councils, policies, statements, reports, guidelines, etc., that may not have the force of law but implement the legal documents in Column 2.
- Column 4, “Defence,” identifies legally enforceable, defence directives and instructions pertaining to the specific type of research that investigators must comply with when conducting human research.
- Column 5, “Defence Research Organisation,” refers to the organisation(s) within the DoD/DND/MoD that are involved with human research. This column identifies the specific DoD/DND/MoD institution guidelines for conducting human research with



respect to the specific type of research that investigators must use to comply with their DoD/DND/MoD references in Column 4.

- Column 6, “Other Government Research Organisations,” cites the references used by non-defence government organisations regarding human research regarding each category of research. These citations may or may not be included in Column 4, Defence. References in this column are important when the TTCP collaboration includes government organizations other than Defence.
- Column 7, “Non-Government Organisations,” lists the policies followed by institutions such as universities, hospitals, companies, etc. with respect to each category of research. References in this column are important when the TTCP collaboration includes non-government organisations.

7.9. I want to collaborate with another nation(s) to share data; what do I need to do?

Tables 5-1 through 5-5 list for each TTCP nation six levels in policy framework (Columns 2–7) covering the requirements for collecting, using, and sharing data for different types of covered research (Column 1).

- Column 1, “Research Elements/Types of Activities,” lists different types of identifiable and non-identifiable data collected by TTCP researchers. Types of activities included are medical, physiological, psychological, naturalistic, surveys, etc.
- Column 2, “Legal Framework,” lists the national laws and acts relevant to each type of human subject research. These legislative elements primarily concern privacy, human rights, health/medicine, safety, and compensation. (see FAQ 7.6)
- Column 3, “National Policy,” identifies councils, policies, statements, reports, guidelines, etc., that may not have the force of law but implement the legal documents in Column 2 regarding the collection, use and sharing of data in ethical research.
- Column 4, “Defence,” identifies legally enforceable, defence directives and instructions pertaining to the collection, use and sharing of data for specific types of research.
- Column 5, “Defence Research Organisation,” refers to the organisation(s) within the DoD/DND/MoD that are involved with human research. This column identifies the specific DoD/DND/MoD institution guidelines for the collection, use and sharing of data.
- Column 6, “Other Government Research Organisations,” cites the references used by non-defence government organisations regarding the collection, use and sharing of data for specific types of human research. These citations may or may not be included in Column 4, Defence. References in this column are important when the TTCP collaboration includes government organizations other than Defence.
- Column 7, “Non-Government Organisations,” lists the policies followed by institutions such as universities, hospitals, companies, etc. with respect to the collection, use and sharing of data. References in this column are important when the TTCP collaboration includes non-government organisations.

7.10. I am collaborating with another TTCP nation(s), is it possible to have one common protocol?

It is probable to harmonize much of the protocol, but it may be difficult to standardize the entire protocol. To support a common protocol or informed consent material, the researchers and



approving ethics boards can attach appendices to the protocol or consent documents for inclusion of unique national information thereby maximizing a common protocol and consent material. TTCP nations have more policies and requirements in common than differences. Early communication with the ethics offices is the key to success.

7.11. I am collaborating with other TTCP nation(s), is it possible to have one common set of informed consent documents?

It is possible. [Chapter 6](#) of the AG25 Final Report (DOC-HUM-2-2008) provides a short description of and references for each nation's informed consent requirements. [Table 6-1](#) lists the key elements required in a consent document by all TTCP nations. To facilitate harmonizing the consent process in collaborative research, the table identifies the minimum common wording or requirements to address in the consent document that is acceptable to all or most nations. These statements or requirements are not in the order they should appear in the consent document; they are grouped by topic. This table does not reflect all of the necessary statements needed to result in fully informing the subject about the research. Additionally, the researchers and approving ethics board can attach appendices to the protocol or consent documents for inclusion of unique national information thereby maximizing a common protocol and consent material.

7.12. I have a question about the human research ethics policies in Australia, who should I contact for help?

1. Secretary ADHREC

LTCOL Rosemary Landy
SO1 Health Policy
CP2-7-129
Northcote Drive
Campbell, ACT, 2600
Australia
Tel.: +61 (03) 6266 3807
Email: rosemary.landy@defence.gov.au

2. Dr. Ken McAnally

Air Operations Division, DSTO
506 Lorimer St, Fishermans Bend, Vic., 3207
Australia
Tel.: +61 (03) 9626 7251
Email: ken.mcanally@dsto.defence.gov.au

3. ANR HUM Group

Dr. Chris Woodruff
Research Leader- Capabilities
Human Protection and Performance Division
Australian Defence Science & Technology Organisation
506 Lorimer St.



Fishermans Bend, Victoria, Australia
Tel.: + 61(03) 9626 7152
Email: Chris.Woodruff@dsto.defence.gov.au

7.13. I have a question about the human research ethics policies in Canada, who should I contact for help?

Chair, Defence Research & Development Canada Human Research Ethics Committee (DRDC HREC)
Defence R&D Canada - Toronto
1133 Sheppard Ave. W., P.O. Box 2000
Toronto, Ontario, Canada M3M 3B9
Tel.: +1 416-635-2000
Fax: +1 416-635-2104
Email: info-toronto@drdc-rddc.gc.ca
Web site: www.toronto.drdc-rddc.gc.ca

7.14. I have a question about the human research ethics policies in New Zealand, who should I contact for help?

Wg Cdr Emma Davis
Director of Psychology, Personnel Branch
Headquarters New Zealand Defence Force
Email: emma.davis@nzdf.mil.nz

7.15. I have a question about the human research ethics policies in the United Kingdom, who should I contact for help?

MoD Research Ethics Committee (MODREC) Secretariat
Email: ethics.sec@dstl.gov.uk
gbarrett@dstl.gov.uk
asrogers@dstl.gov.uk

7.16. I have a question about the human research ethics policies in the United States, who should I contact for help?

Patty Decot
Tel.: 1-703-588-7402, DSN 425-7402
Email: patty.decot@osd.mil
Web site: www.dtic.mil/biosys



8. CONCLUSION

TTCP (and its predecessor committees) has been very successful at providing a framework to facilitate collaboration in defence science and technology. The MOU allows researchers to share information and promotes joint research. Although there are TTCP templates for project agreements and data exchange agreements, there are no templates for a universally acceptable research protocol or consent document.

AG25 was formed to review each nation's policies and procedures for approving research involving human subjects and to develop guidance to facilitate TTCP members in obtaining their nation's approval for collaborative projects. In this report, AG25 has summarized each TTCP nation's policy environment for research involving human subjects. The report summarizes each nation's policies for protocol review and approval, focusing on international collaboration. Additionally, AG25 concluded there were four specific areas of human research protection that frequently rose to the attention of the National Representatives and are most impacted by differing national policies: liability consideration, applicability of the national policy to various kinds of activities, sharing data, and having a common informed consent document.

This report provides all of the information and references necessary to develop a research protocol that is compliant with policies of each nation. When designing collaborative research, it is critical that the principal national researchers understand their nation's requirements and know whom to contact for assistance. TTCP nations, because their policies are based on the same ethical principals of beneficence, justice, and respect for persons, have similar regulatory requirements. In each nation, implementation of the national policies is left to the research organisations and ethics boards. For example, each nation's policies require the informed consent process to provide the research subject with written documentation, and this information transfer process has to clearly explain the specific elements of the research study to the participant. The policies rarely state the exact language that must be used to address each element. It is this latitude that the ethics boards and research institutions need to use to facilitate collaborative research. The researchers might need to help their institution and ethics board understand the true national requirements, the need for flexibility in applying the policies, and the regulatory framework of the collaborating nations.

If a TTCP researcher is collaborating at one location, the requirements of the host nation may take precedence over the national policies of the visiting TTCP member. If the visiting TTCP member is acting as a "researcher," multinational review of the protocol might be necessary. The visiting researcher should contact their ethics board as early as possible for a determination. If a review is required, the visiting researcher's ethics board should review the research with an appreciation of the limited role their researcher and their nation has in the study. Finally, in the case where the visiting TTCP member is only acting as an "observer," multinational review of the protocol should not be necessary.

The key to an efficient review and approval process for collaborative research is early involvement of each nation's approving office. The approving offices can work together to help identify a logical process for research approval, agree to common elements of the protocol and informed consent material, identify a lead country (if applicable), and share a scientific review,



etc. To support a common protocol or informed consent material, the researchers and approving ethics board can attach appendices to the protocol or consent documents for inclusion of unique national information thereby maximizing a common protocol and consent material.

AG25 has developed a basic set of Frequently Asked Questions (FAQ) to assist TTCP researchers to understand the requirements and process for ethical review of human subject research. The FAQ will also be posted on the TTCP Portal where they will be a living document and updated by the HUM Group as necessary. Additionally, all of the relevant national policies regarding human subject research are listed in this report. The reference titles are hyperlinked to the actual document on the World Wide Web.

Although this report concludes the work of AG25 at this time, the AG can be reconstituted by the HUM Group Chair to address other human subject research matters or to assist TTCP researchers.



9. REFERENCES

TTCP 201 (former POPNAMRAD), DOC-SEC-02-2007
<http://www.dtic.mil/ttcp/>

TTCP MOU
https://www.ttcp.drdc-rddc.gc.ca/ev_en.php?ID=1189_201&ID2=DO_TOPIC

9.1. National References for Australia

Declaration of Helsinki
<http://www.wma.net/e/policy/b3.htm>

Defence Act 1903
<http://www.comlaw.gov.au/comlaw/management.nsf/lookupindexpagesbyid/IP200401433>

Public Service Act 1999
<http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/current/bytitle/9FB97726419A11C0CA25741A0003D994?OpenDocument&mostrecent=1>

Occupational Health and Safety (Commonwealth Employment) Act 1991
<http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/frame1odgmentattachmen ts/516D6E419A98E619CA25717E00180CE5>

Safety Rehabilitation and Compensation Act 1988
http://www.austlii.edu.au/au/legis/cth/consol_act/sraca1988368/

Privacy Act 1988
http://www.austlii.edu.au/privacy/Privacy_Act_1988/

National Health and Medical Research Council (NHMRC) Act 1992
<http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/4AFACF8FAAF9ED97CA25719C0081EF9F?OpenDocument>

Therapeutic Goods Act 1989
<http://www.comlaw.gov.au/comlaw/Legislation/ActCompilation1.nsf/0/3342878B16531244CA25748D000A0A65?OpenDocument>

National Statement on Ethical Conduct in Human Research
http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf

Australian Code for the Responsible Conduct of Research
<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>



Australian Defence Human Research Ethics Committee (ADHREC)
<http://www.defence.gov.au/health/research/adhrec/i-adhrec.htm>

Defence Instruction (General) Administration 24-3 Conduct of Human Research in Defence
http://www.defence.gov.au/health/research/adhrec/docs/GA24_03.pdf

Defence Science and Technology Organisation (DSTO)
<http://www.dsto.defence.gov.au/>

Health Manual volume 23 Human Research in Defence – Instructions for Researchers
http://www.defence.gov.au/health/research/adhrec/i-adhrec_docs.htm

Military Rehabilitation and Compensation Act
<http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/current/bytitle/7EC7CE1A4E87CE73CA25741D001482A6?OpenDocument&mostrecent=1>

Occupational Health and Safety Act 1991
<http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/current/bytitle/AA734F66C0A218AAC2572C1007CDA88?OpenDocument&mostrecent=1>

9.2. National References for Canada

DAOD 5061-0: Research Involving Human Subjects
http://www.admfincs.forces.gc.ca/admfincs/subjects/daod/5061/0_e.asp

DAOD 5061-1: Research Involving Human Subjects - Approved Procedures
http://www.admfincs.forces.gc.ca/admfincs/subjects/daod/5061/0_e.asp

Survey Coordination in DND/CF CANFORGEN 198/08 ADMHRMIL 079 UNCLASS 131028Z DEC 02
http://vcds.dwan.dnd.ca/vcde-exec/pubs/canforgen/2008/198-08_e.asp

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. 1998 (with 2000, 2002 and 2005 amendments)
<http://www.pre.ethics.gc.ca>

DRDC Guidelines for Human Participation in Research Projects, Defence R&D Canada – Toronto, 01 April 2003
<http://www.toronto.drde-rddc.gc.ca>

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Washington, D.C., 1979 (1998 update)
<http://www.ohsr.od.nih.gov/guidelines/belmont.html>



World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects
<http://www.wma.net/e/policy/b3.htm>

CIHR Best Practices for Protecting Privacy in Health Research, Canadian Institutes of Health Research, September 2005
<http://www.cihr-irsc.gc.ca>

Privacy Act (R.S., 1985, c. P-21)
<http://laws.justice.gc.ca/en/P-21/index.html>

Canadian Human Rights Act (R.S., 1985, c. H-6)
<http://laws.justice.gc.ca/en/H-6/index.html>

Canadian Charter of Rights and Freedoms (Schedule B, Constitution Act, 1982)
<http://laws.justice.gc.ca/en/Charter/index.html>

Canadian Institutes of Health Research Act (2000, c. 6)
<http://laws.justice.gc.ca/en/C-18.1/index.html>

National Defence Act (R.S., 1985, c. N-5)
<http://laws.justice.gc.ca/en/N-5/index.html>

Government Employees Compensation Act (R. S., 1985, c. G-5)
<http://laws.justice.gc.ca/en/G-5/>

Canadian Labour Code (R.S., 1985, c. L-2)
<http://laws.justice.gc.ca/en/L-2/>

Compensation and Benefits Instructions (CBI) 205.48
http://www.dnd.ca/dgcb/cbi/engraph/cbi_chapter-205_e.asp

9.3. National References for New Zealand

Health & Safety in Employment Act 1992
<http://www.legislation.govt.nz>

Health Practitioners Competence Assurance Act 2003
<http://www.legislation.govt.nz>

Human Rights Act 1993
<http://www.legislation.govt.nz>

Declaration of Helsinki
<http://www.wma.net/e/policy/b3.htm>



[Privacy Act 1993](#)

<http://www.legislation.govt.nz>

[The Official Information Act 1982](#)

<http://www.legislation.govt.nz>

[Injury Prevention, Rehabilitation, and Compensation Act 2001 No 49, Public Act](#)

<http://www.legislation.govt.nz>

Defence Force Order 21/2002, Authority to Conduct Research

Defence Force Order 15/2003

Defence Force Order 10/2003

[Social Policy Evaluation & Research \(SPEaR\)](#)

www.msd.govt.nz

Defence Force Order 15/2003, Use of information gathered by NZDF Psychologists

Defence Force

<http://www.nzdf.govt.nz>

Defence Force Order 10/2003, The Privacy Act 1993 NZDF Procedures and Practices

[Health \(Retention of Health Information\) Regulations 1996](#)

<http://www.legislation.govt.nz>

[Health Information Privacy Code 1994](#)

<http://www.legislation.govt.nz>

[Health and Disability Commissioner \(Code of Health and Disability Services Consumers' Rights\) Regulations 1996 \(SR 1996/78\) \(as at 03 September 2007\)](#)

<http://www.legislation.govt.nz>

[HPCA Act](#)

<http://www.legislation.govt.nz>

[New Zealand Psychological Society Code of Ethics](#)

<http://www.psychologistsboard.org.nz>

[Health and Safety in Employment Act 1992](#)

<http://www.legislation.govt.nz>



9.4. National References for the United Kingdom

Ethical Conduct and Scrutiny in MoD Research involving Human Participants
http://www.science.mod.uk/ethics/content/ethics_jsp_536.pdf

Declaration of Helsinki
<http://www.wma.net/e/policy/b3.htm>

Medicines for Human Use (Clinical Trials) Regulations 2004
<http://www.opsi.gov.uk/si/si2004/20041031.htm>

Freedom of Information Act 2000
http://www.opsi.gov.uk/Acts/acts2000/ukpga_20000036_en_1

Data protection act (1998)
http://www.opsi.gov.uk/Acts/acts1998/ukpga_19980029_en_1

Human Rights Act 1998
http://www.opsi.gov.uk/ACTS/acts1998/ukpga_19980042_en_1

Census (Confidentiality) Act 1991
http://www.england-legislation.hmso.gov.uk/acts/acts1991/Ukpga_19910006_en_1

Access to Health Records Act 1990
http://www.opsi.gov.uk/acts/acts1990/ukpga_19900023_en_1

Health and Safety at Work Act 1974
<http://www.hse.gov.uk/legislation/hswa.htm>

BPS Code of Ethics and Conduct 2006
[http://www.bps.org.uk/document-download-area/document-download\\$.cfm?file_uuid=5084A882-1143-DFD0-7E6C-F1938A65C242&ext=pdf](http://www.bps.org.uk/document-download-area/document-download$.cfm?file_uuid=5084A882-1143-DFD0-7E6C-F1938A65C242&ext=pdf)

Human Tissues Act of 2004
<http://www.opsi.gov.uk/acts/acts2004/20040030.htm>

National Research Ethics Service (NRES)
<http://www.nres.npa.nhs.uk>

DEFCON 705
<http://www.aof.mod.uk/aofcontent/tactical/toolkit/downloads/defcons/pdf/705.pdf>



9.5. National References for the United States

"Health Insurance Portability and Accountability Act" (HIPAA), Public Law 104-191 and 45 Code of Federal Regulations Parts 160,162, and 164 (45 CFR 160, 162, and 164)
<http://en.wikipedia.org/wiki/HIPAA>

"Privacy Act of 1974", Section 522a of Title 5, United States Code (5 USC 522a) and Public Law 93-579
http://en.wikipedia.org/wiki/Privacy_Act_of_1974

"Employment of Experts and Consultants, Temporary or Intermittent," Section 3109 of Title 5, United States Code (5 USC 3109)
<http://uscode.house.gov/uscode-cgi/fastweb.exe?getdoc+uscview+t05t08+204+0++%28%29%20%20AND%20%28%285%29%20ADJ%20USC%29%3ACITE%20AND%20%28USC%20w%2F10%20%283109%29%29%25>

"Limitation on use of humans as experimental subjects" Section 980 of Title 10, United States Code (10 USC 980)
<http://uscode.house.gov/uscode-cgi/fastweb.exe?getdoc+uscview+t09t12+632+0++%28%29%20%20AND%20%28%2810%29%20ADJ%20USC%29%3ACITE%20AND%20%28USC%20w%2F10%20%28980%29%29%3ACITE%20%20%20%20%20%20%20%20%20%20>

US Federal Policy for the Protection of Human Subjects, (US Government-wide, "Common Rule"):

"Protection of Human Subjects," (US Department of Defense-specific), 32 Code of Federal Regulations Part 219 (32 CFR 219)
http://www.access.gpo.gov/nara/cfr/waisidx_01/32cfr219_01.html

"Protection of Human Subjects," (US Department of Health and Human Services-specific and used by civilian institutions), 42 Code of Federal Regulations Part 46 (46 CFR 46)
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

"Food and Drugs," Food and Drug Administration (FDA), 21 Code of Federal Regulations Parts 50, 56, 312, 600, and 812
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

DoD Directive 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"
<http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>

DoD Instruction 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defence Force Health Protection Programs"
<http://www.dtic.mil/whs/directives/corres/pdf/620002p.pdf>



DoD Directive 6000.8, "Funding and Administration of Clinical Investigation Program"
<http://www.dtic.mil/whs/directives/corres/html/600008.htm>

DoD Regulation 5400.11-R, "Department of Defence Privacy Program"
<http://www.dtic.mil/whs/directives/corres/html/540011r.htm>

DoD 8580.02-R, "DoD Health Information Security Regulation"
<http://www.dtic.mil/whs/directives/corres/pdf/858002rp.pdf>

DoD Instruction 1100.13, "Surveys of DoD Personnel"
<http://www.dtic.mil/whs/directives/corres/pdf/110013p.pdf>

Army Regulation 70-25, "Use of Volunteers as Subjects of Research"
http://www.army.mil/usapa/epubs/pdf/r70_25.pdf

Secretary of Navy Instruction 3900.39D, "Human Research Protection Program"
<http://navymedicine.med.navy.mil/Files/Media/ecm/sitedata/BC325237-802E-D019-A78AF9A6F4DF4282/library/SECNAVINST%203900-39D%20-%206%20Nov%2006.pdf>

US Air Force Instruction 40-402, "Army Protection of Human Subjects in Biomedical Research"
<http://www.e-publishing.af.mil/shared/media/epubs/AFI40-402.pdf>



10. GLOSSARY

Acronym	Definition	Country
AC Pers	Assistant Chief of Personnel	NZ
ACC	Accident Compensation Corporation	NZ
ADF	Australian Defence Force	AS
ADHREC	Australian Defence Human Research Ethics Committee	AS
AG	Action Group	
APS	Australian Public Service	AS
ARC	Australian Research Council	AS
AS	Australia	AS
AVCC	Australian Vice-Chancellors' Committee	AS
BPS	British Psychological Society	UK
CA	Canada	CA
CANFORGEN	Canadian Forces General Order	CA
CBI	Compensation and Benefits Instructions	CA
CDSI	Chief Defence Scientist Instruction	AS
CFR	Code of Federal Regulations	US
CMP	Chief of Medical Personnel	CA
Common Rule	Federal Policy for the Protection of Human Subjects (32 CFR 219)	US
COREC	Central Office for NHS Research Ethics Committees	UK
DAOD	Defence Administrative Order and Directive	CA
DC	Data Collection	CA
DDR&E	Director of Defense Research and Engineering	US
DEFCONs	Defence Contracts	UK
DFO	Defence Force Order	NZ
DGMPRA	Director General Military Personnel Research and Analysis	CA
DGMS	Director General Medical Services	NZ
DHHS	Department of Health and Human Services	US
DI	Defence Instruction	AS
DND	Department of National Defence	CA
DoD	Department of Defense	US
DoDD	DoD Directive	US



Acronym	Definition	Country
DRDC	Defence Research and Development Canada	CA
DS&C	Directorate of Safety and Claims	UK
DSTO	Defence Science and Technology Organisations	AS
DTA	Defence Technology Agency	NZ
FAQ	Frequently Asked Questions	
FDA	Food and Drug Administration	US
GoC	Government of Canada	CA
GP	General Practitioner	UK
HIPAA	Health Insurance Portability and Accountability Act	US
HPCA Act	Health Practitioners Competence Assurance Act	NZ
HREC	Human Research Ethics Committee	AS
HSE Act	Health and Safety in Employment Act	NZ
HSR	Human Subject Research	
HUM Group	Human Resources and Performance Group	
IC	Informed Consent	
ICD	Informed Consent Document	US
IPRC Act	Injury Prevention, Rehabilitation and Compensation Act	NZ
IRB	Institutional Review Board	US
JSP	Joint Service Publication	UK
LREC	Local Research Ethics Committee	UK
MoD	Ministry of Defence	UK
MoDREC	MoD Research Ethics Committee	UK
MOU	Memorandum of Understanding	
MREC	Multicentre Research Ethics Committee	UK
National Statement	National Statement on Ethical Conduct in Human Research	AS
NCEHR	National Council on Ethics in Human Research	CA
NHMRC	National Health and Medical Research Committee	AS
NHS	National Health Service	UK
NRES	National Research Ethics Service	UK
NZ	New Zealand	NZ
NZDF	New Zealand Defence Force	NZ



Acronym	Definition	Country
OH&S Act	Occupational Health and Safety Act 1991	AS
PA	Project Arrangement	
POC	Point of Contact	
POP NAMRAD	Policies, Organisation and Procedures in Non-Atomic Military Research and Development	
PWGSC	Public Works and Government Services Canada	CA
R&D	Research and Development	
RDT&E	Research, Development, Test, and Evaluation	
REB	Research Ethics Board	CA
SECNAVINST	Secretary of Navy Instruction	US
SES	State Emergency Service(s)	AS
SOP	Standard Operating Procedure	
SPEaR	Social Policy Evaluation & Research	NZ
SRC	Safety, Rehabilitation and Compensation Act 1988	AS
SUD	Secondary Use of Data	CA
TB	Treasury Board	CA
TCPS	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans	CA
TTCP	The Technical Cooperation Program	
UK	United Kingdom	UK
US	United States of America	US
USC	United States Code	US



APPENDIX 1. Additional UK National Policies

Declaration of Helsinki:

Declaration of Helsinki is a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects (includes research on identifiable human material or identifiable data.)

The main duty of the physicians is to promote and safeguard the health, safety, dignity and privacy of the human subjects. This duty of care towards subjects should take precedence over the interests of science.

It is stated that all medical research is subject to ethical standards that promote the respect of all human rights and that it must be recognised that some populations are more vulnerable than others and must be given special considerations.

The Declaration of Helsinki also outlines that all research investigators must be aware of all ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements.

Medical research should not be carried out without a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and where appropriate, animal experimentation.

Even though the subject will have consented to participating in the research, the responsibility for the welfare of the subject must always lie with the medically qualified and clinically competent person.

All risks and burdens must be assessed against the foreseeable benefits of the research, on doing this research should then only be carried out if the risks are deemed manageable and do not outweigh the benefits.

All subjects must be volunteers and be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, the anticipated benefits and potential risks of the study and the discomfort it may entail. Participants must also be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. Freely given, informed consent must then be obtained from the participant (preferably in writing).

Authors and publishers also have ethical obligations, in the publication of results of research; the investigators are obliged to preserve the accuracy of the results. Sources of funding, institutional affiliations and any possible conflicts of interest should also be declared in the publication.



Medicines for Human Use (Clinical Trials) Regulations 2004:

Research involving medicines is regulated under the Medicines Act and the Medicines for Human Use (Clinical Trials) Regulations. All trials of new medicinal products, or new therapeutic approaches using previously-tested medicinal products, on people must be authorized by the Medicines and Healthcare Products Regulatory Agency (MHRC) who offer advice and undertake advisory inspections for such trials and the preparation of products used in them. There are statutory instructions for Good Clinical Practice in such trials. The same Agency regulates research involving new medical devices. Clinical trials will generally require approval from a local NHS REC. Research protocols submitted to MHRC must also be submitted to MODREC.

Freedom of Information Act 2000:

Anyone may make a request for information to any public authority provided it is in writing, states the name and address of the enquirer and describes the information requested.

The authority has the “duty to confirm or deny” whether or not it holds the information, and if it does, to supply it within 20 working days from receipt of request (there are certain exceptions to this).

Authorities are not obliged to provide information where they cannot find it without assistance and can make reasonable enquiries of the applicant in order to identify and locate the information requested.

If information cannot be supplied then the authority has a duty to advise and assist the enquirers in accessing the information.

An applicant may request to have the information in a particular format, the authority is obliged to do so wherever practical or explain why it cannot.

There are two general types of exemption:

Absolute exemptions – those where there is no duty to consider the public interest.

Qualified exemptions – those where, even though an exemption exist, an authority has a duty to consider whether disclosure is required in the public interest.

The public interest test is one where the authority assesses whether the public interest in withholding the information outweighs the public interest in disclosing the information by considering the circumstances of each particular case in the light of the potential exemption which might be claimed.

Data Protection Act (1998):

Personal data must be obtained fairly and lawfully. The data subject should be informed of who the data controller is; who the data controller’s representative is; the purpose(s) for which the data are intended to be processed and to whom the data will be disclosed.



Personal data processing may only take place if specific conditions have been met – these include the subject having given consent and of the processing being necessary for the legitimate interests of the data controller. Additional conditions must be satisfied for the processing of sensitive personal data (for example, relating to ethnicity, political opinion, religion, trade union membership, health, sexuality, or criminal record of the data subject).

The new Act covers personal data in both electronic and manual form, and whether the data are held in a relevant, structured filing system.

Personal data processing must be in accordance with the purposes notified to the data protection commissioner – if any new processing is to take place then the data protection representative must be consulted.

Personal data must be kept accurate and up to date and shall not be kept for longer than is necessary.

Appropriate security measures must be taken against unlawful or unauthorised processing of personal data and against accidental loss of/damage to personal data. These include both technical measures (e.g. data encryption, regular backing-up of data files) and organisational measures (e.g. staff training in the Data Protection Act).

Personal data shall not be transferred to a country outside the European Economic Area unless specific exemptions apply (e.g. if the data subject had given consent) this includes the publication of personal data on the internet.

Human Rights Act 1998:

The Human Rights Act makes a remedy available for any breach of a convention right without having the need to go to the European Court of Human Rights; it is because of the Human Rights Act that the death penalty in UK law was abolished.

The Act makes it unlawful for any public body to act in a way which is incompatible with the Convention, unless the wording of an Act of Parliament means they have no other choice.

The following rights are stated under the Human Rights Act 1998 as taken from the Convention Rights:

- Right to life
- Prohibition on torture
- Prohibition on slavery and forced labour
- Right to liberty and security
- Right to a fair trial
- No punishment without law
- Right to respect for private and family life
- Freedom of thought, conscience and religion
- Right to freedom of expression



Freedom of assembly and association
Right to marry and raise a family
Prohibition on discrimination

Census (Confidentiality) Act 1991:

The Census (Confidentiality) Act regards any disclosure of personal information without lawful authority shall be considered an offence.

Access to Health Records Act 1990:

The Access to Health Records Act establishes the “right of access to health records by the individuals to whom they relate and other persons; to provide for the correction of inaccurate health records; for the avoidance of certain contractual obligations; and for connected purposes.”

It defines a health record as consisting of information relating to the physical or mental health of an individual who can be identified from that information, or from that and other information in the possession of the holder of the record.

The holder of the information is usually a health professional (e.g. a general practitioner).

An application for access to a health record can be made by:

The patient

A person authorised in writing to make the application on the patient’s behalf

A person who has parental responsibility for a patient who is under the age of 16

A person appointed by the courts if the patient is incapable of managing their own affairs

A personal representative of a deceased patient.

Records will not be released to any individual other than the patient when the information contained may cause serious harm to the physical or mental health of the patient or of any other individual.

Health and Safety at Work Act 1974:

This legislation is aimed principally at people and their work activities instead of premises and processes. The legislation includes both the protection of people at work and the prevention of risk to the health and safety of the general public, which may arise from work activities.

Human Tissue Act 2004

A licence is required for removal of tissue and for retention and use of tissue.



APPENDIX 2. Canadian Forces General Order 198/08

CANFORGEN 198/08 CMP 084/08 271214Z OCT 08

COORDINATION OF DND/CF OPINION AND INFORMATION GATHERING AND SOCIAL SCIENCE RESEARCH

UNCLASSIFIED

REFS: A. [CANFORGEN 145/02 ADMHRMIL 079 UNCLASS 131028Z DEC 02](#)
B. DGMPPRA SOP 1000-9 SOCIAL SCIENCE RESEARCH REVIEW BOARD
C. COMMUNICATIONS POLICY OF THE GOVERNMENT OF CANADA, POLICY REQUIREMENT, ITEM 8
D. GOVERNMENT OF CANADA CONTRACTING POLICY

1. REF A IS CANCELLED AND SUPERCEDED BY THIS MESSAGE WHICH OUTLINES NEW DEVELOPMENTS IN PUBLIC OPINION AND SURVEY RESEARCH COORDINATION
2. OPINION AND INFORMATION GATHERING OR SOCIAL SCIENCE RESEARCH REFER TO ANY RESEARCH PROGRAMME UNDERTAKEN ON BEHALF OF DND AND THE CF INVOLVING A DATA COLLECTION INSTRUMENT AND PROCESS THAT SOLICITS RESPONSES FROM INDIVIDUALS, WHETHER THE RESEARCH BE UNDERTAKEN WITH CF PERSONNEL, THEIR FAMILIES, ANY SEGMENT OF THE CANADIAN POPULATION OR ANY OTHER AUDIENCE WITHIN OR OUTSIDE CANADA. RESPONSES MAY TOUCH UPON THEIR THOUGHTS, FEELINGS, AND BEHAVIOURS. PROCESSES CAN INCLUDE BUT ARE NOT LIMITED TO: MAIL-OUT/MAIL-BACK QUESTIONNAIRES, ELECTRONIC QUESTIONNAIRES, PAPER-AND-PENCIL SURVEYS, FOCUS GROUPS, INDIVIDUAL FACE-TO-FACE INTERVIEWS, TELEPHONE INTERVIEWS, AND PARTICIPANT OBSERVATION. THE FOLLOWING RESEARCH AND/OR METHODS FOR OBTAINING OPINIONS AND/OR ADVICE ARE NOT CONSIDERED TO BE OPINION RESEARCH: LITERATURE REVIEWS OR REVIEWS OF SECONDARY SOURCES, INCLUDING REVIEWS OF ALREADY CONDUCTED PUBLIC OPINION RESEARCH, SECONDARY ANALYSIS OF PREVIOUSLY COLLECTED PUBLIC OPINION RESEARCH DATA, COURSE CRITIQUES AND VERIFICATION OF PERFORMANCE OF SERVICES OR DELIVERY OF GOODS IN CONTRACT SITUATIONS
3. THE CONSTANT FLOW OF REQUESTS TO PARTICIPATE IN RESEARCH IS INCREASING THE INCIDENCE OF REFUSALS BECAUSE OF SURVEY FATIGUE. IF NOT CONTROLLED, THESE PRACTICES WILL DIMINISH THE ABILITY OF THE DEPARTMENT/CF TO RELY ON SURVEY RESULTS TO INFORM POLICY AND CREATE/MONITOR ESSENTIAL PROGRAMMES



4. DND AND THE CF ARE COMMITTED TO OPINION AND INFORMATION GATHERING AND SOCIAL SCIENCE RESEARCH OF THE HIGHEST STANDARDS. WITH A RIGOROUS SCREENING OF ALL PROPOSED RESEARCH, THE RESEARCH WHICH IS FINALLY SELECTED:
 - A. WILL CONFORM TO THE DIRECTION, POLICIES, PRIORITIES AND EXPENDITURE CEILINGS AND ORGANIZATIONAL AIMS OF THE GOVT OF CANADA, DND AND THE CF
 - B. WILL DEMONSTRATE VALUE TO DND, THE CF AND THE LEVEL 1 ADVISOR (L1) ORGANIZATIONS IN WHICH THE RESEARCH IS TO BE CONDUCTED
 - C. WILL NOT CONFLICT OR OTHERWISE INTERFERE WITH HIGHER PRIORITY EFFORTS WITHIN DND, THE CF OR APPLICABLE L1 ORGANIZATIONS, AND
 - D. WILL BE CONDUCTED IN ACCORDANCE WITH ACCEPTED PROFESSIONAL PRACTICES
5. POLICY. CMP AND ADM(S AND T) SHARE AUTHORITY FOR SOCIAL SCIENCE RESEARCH CONDUCTED BY OR FOR DND/CF, WHILE ADM (PA) HAS AUTHORITY FOR MANAGING PUBLIC OPINION RESEARCH. DIRECTOR GENERAL MILITARY PERSONNEL RESEARCH AND ANALYSIS (DGMPRA), ON THEIR BEHALF, IS RESPONSIBLE FOR THE COORDINATION OF ALL OPINION AND SURVEY RESEARCH WITHIN DND/CF.
 - A. QUALITY CONTROL AND TECHNICAL APPROVAL IS REQUIRED FOR ALL OPINION AND INFORMATION GATHERING OR SOCIAL SCIENCE RESEARCH THAT INVOLVES DND EMPLOYEES, CF PERSONNEL OR THEIR FAMILIES, OR CF APPLICANTS AS PARTICIPANTS WITH THE EXCEPTION OF EXEMPTED AGENCIES SET OUT IN REF B.
 - B. PROPOSALS ARE REVIEWED BY THE DGMPRA SOCIAL SCIENCE RESEARCH REVIEW BOARD AND APPROVED BY DGMPRA RESEARCH STEERING COMMITTEE. THE APPROVAL IS BASED ON THE TECHNICAL MERITS OF THE PROJECTS, INCLUDING ETHICS, DESIGN, METHODOLOGY, APPROPRIATE SAMPLE SIZE, RELEVANCE AND TIMING
6. OPINION AND INFORMATION GATHERING OR SOCIAL SCIENCE RESEARCH THAT INVOLVES DND EMPLOYEES, CF PERSONNEL OR THEIR FAMILIES, OR CF APPLICANTS AS PARTICIPANTS SHALL NOT BE INITIATED WITHOUT THE APPROVAL OF CMP AND THE LEVEL 1 ADVISOR (L1) OF THE PARTICIPANTS. CMP IS THE APPROVAL AUTHORITY FOR CF



APPLICANTS. ADM(PA) IS APPROVAL AUTHORITY FOR ALL STUDIES CONDUCTED WITH CANADIANS, OTHER THAN THOSE INDICATED ABOVE

7. PUBLIC OPINION RESEARCH (POR) IS DEFINED AT REF C. ITEM 16.13 OF REF D IDENTIFIES PWGSC AS THE SOLE AUTHORITY RESPONSIBLE TO CONTRACT FOR POR. FURTHERMORE, A GOVT OF CANADA DIRECTIVE ON POR EXPENDITURE CONTROLS REQUIRES MINISTERIAL APPROVAL ON ALL CONTRACTED POR PRIOR TO CONTRACTING. OWING TO THE DEPARTMENTAL EXPENDITURE CEILING DECREED BY THE GOVT, AGENCIES ARE STRONGLY ENCOURAGED TO USE INTERNAL RESOURCES INSTEAD OF EXTERNAL CONTRACTS, WHERE POSSIBLE. FOLLOWING REVIEW AND APPROVAL OF POR PROJECT PROPOSALS BY DGMPPRA, ADM (PA) IS RESPONSIBLE FOR APPROVING THOSE REQUESTS THAT REQUIRE CONTRACTING PRIOR TO BEING SUBMITTED FOR MINISTERIAL APPROVAL
8. UNAUTHORIZED SURVEY RESEARCH WILL NOT BE TOLERATED. IT IS BOTH A BREACH OF REGULATIONS AND UNETHICAL. UNAUTHORIZED RESEARCH MAY THEREFORE BE SUBJECT TO INVESTIGATION AND DISCIPLINARY ACTION AS REQUIRED. AUTHORIZED OPINION AND SURVEY RESEARCH INSTRUMENTS WILL HAVE A DGMPPRA AUTHORIZATION NUMBER ON THE FIRST PAGE
9. QUESTIONS REGARDING SURVEY COORDINATION MAY BE DIRECTED THROUGH THE CHAIN OF COMMAND TO THE DGMPPRA RESEARCH COORDINATOR, AT (613) 996-3305 OR TO [CMP-SURVEYCOORDINATION\(AT SIGN\)FORCES.GC.CA](mailto:CMP-SURVEYCOORDINATION(AT SIGN)FORCES.GC.CA). DOCUMENTATION MAY BE DOWNLOADED FROM THE DGMPPRA SURVEY COORDINATION WEBSITE AT [HTTP://HR.OTTAWA-HULL.MIL.CA/DGMP/DMPORA/ENGRAPH/SURVEYS \(UNDERScore\) E.ASP/SEC\(EQUAL SIGN\)4](http://HR.OTTAWA-HULL.MIL.CA/DGMP/DMPORA/ENGRAPH/SURVEYS (UNDERScore) E.ASP/SEC(EQUAL SIGN)4)
10. SIGNED BY MGEN W. SEMIANIW, CMP,

Last Updated: 2008-10-27

Important notices

Accessed http://vcds.dwan.dnd.ca/vcds-exec/pubs/canforgen/2008/198-08_e.asp on 2008-11-05